# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2002

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o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from

to

Commission file number: 0-19311

## IDEC PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

33-0112644

(I.R.S. Employer Identification No.)

3030 Callan Road, San Diego, California

(Address of principal executive offices)

92121

(Zip code)

(858) 431-8500

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, \$0.0005 par value**(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 🗵 No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes 🗵 No o

As of June 30, 2002, the aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$5,202,590,172. (Based upon the "closing" price as reported by The Nasdaq Stock Market on June 28, 2002). This number is provided only for the purposes of this report and does not represent an admission by either the Registrant or any such person as to the status of such person.

As of January 31, 2003, the Registrant had 154,677,126 shares of its common stock, \$0.0005 par value, issued and outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its Annual Meeting of Stockholders to be held on May 19, 2003 are incorporated by reference into Part III.

#### IDEC PHARMACEUTICALS CORPORATION

#### ANNUAL REPORT ON FORM 10-K

## FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002

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#### PART I

## Item 1. Business.

#### Overview

IDEC Pharmaceuticals Corporation is a biopharmaceutical company engaged primarily in the research, development, manufacture and commercialization of targeted therapies for the treatment of cancer and autoimmune and inflammatory diseases. Our two commercial products, Rituxan® (rituximab) and Zevalin® (ibritumomab tiuxetan), are for use in the treatment of certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs. B-cell NHLs currently afflict approximately 300,000 patients in the United States. We are also developing products for the treatment of cancer and various autoimmune and inflammatory diseases, such as rheumatoid arthritis, allergic asthma and allergic rhinitis.

In November 1997, Rituxan became the first monoclonal antibody approved by the United States Food and Drug Administration, or FDA, for a cancer therapy indication. Rituxan, marketed in the United States under a copromotion arrangement between us and Genentech, Inc., achieved U.S. net sales of \$1.08 billion in 2002, compared to \$779.0 million in 2001, an increase of 39%. F. Hoffmann-La Roche Ltd., or Roche, sells rituximab outside the United States, except in Japan where it copromotes Rituxan in collaboration with Zenyaku Kogyo Co. Ltd., or Zenyaku.

Under our copromotion arrangement with Genentech, we share responsibility with Genentech for selling and continued development of Rituxan in the United States. Continued development of Rituxan includes conducting supportive research and post-approval clinical studies on Rituxan and obtaining potential approval of Rituxan for additional indications. Genentech provides support functions for the commercialization of Rituxan including marketing, customer service, order entry, distribution, shipping and billing. Since September 1999, Genentech has been responsible for all worldwide manufacturing of Rituxan.

All U.S. sales of Rituxan and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis. Our profit-sharing formula with Genentech has two tiers; we earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We began recording our profit share at the higher percentage during the first quarter of both 2002 and 2001.

Rituxan, which is delivered intravenously, is approved as a treatment of relapsed or refractory low-grade or follicular, CD20-positive, B-cell NHL. Typically, treatment with Rituxan is administered as four weekly intravenous infusions over a 22-day period compared to other available therapies, such as chemotherapy, which are typically administered in repeated cycles for four to eight months. Because of its proven benefits and safety profile, we believe that Rituxan is a strong candidate for combination therapy, and we are currently researching its possible uses in this role.

In May 2001, we announced that the FDA approved a Supplemental Biological License Application, or sBLA, for Rituxan. The new product labeling allows for:

- retreatment with Rituxan after a prior course of Rituxan therapy;
- treatment with eight weekly infusions of Rituxan, as an alternative to the prior approved labeling of four weekly infusions; and
- treatment of NHL patients with bulky disease (tumors greater than ten centimeters).

In June 1998, Roche, our European marketing partner for Rituxan, was granted marketing authorization for Rituximab in all European Union countries. In March 2002, the European Medicines Evaluation Agency, or EMEA, approved the use of Rituximab in combination with standard

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chemotherapy, or CHOP, to treat patients with intermediate/high grade NHL. In June 2001, Zenyaku, our Japanese marketing partner for Rituxan, was granted marketing authorization for Rituxan in Japan. Rituxan is the trade name in the United States, Canada and Japan for the compound Rituximab. Outside the United States, Canada and Japan, Rituximab is marketed as MabThera. In this Form 10-K, we refer to Rituximab, Rituxan and MabThera collectively as Rituxan, except where we have otherwise indicated.

Initial results of a Roche sponsored Phase II blinded, randomized, controlled study of Rituxan plus steroids alone or in combination with methotrexate or cyclophosphamide in rheumatoid arthritis were presented at the American College of Rheumatology Meeting in 2002. These results suggest that Rituxan had significant activity in rheumatoid arthritis. We, in conjunction with Genentech and Roche, are now pursuing Phase III trials and additional Phase II trials in this indication.

In February 2002, Zevalin became the first radioimmunotherapy approved by the FDA for the treatment of certain B-cell NHLs. Zevalin, which is delivered intravenously, is approved as a treatment for relapsed or refractory low-grade, follicular, or transformed B-cell NHL including patients with Rituxan refractory follicular NHL. We commenced selling Zevalin in April 2002 and achieved U.S. net sales of \$13.7 million in 2002. We have retained all U.S. marketing and distribution rights to Zevalin and have granted marketing and distribution rights outside the U.S. to Schering Aktiengesellschaft, or Schering AG. In January 2001, the EMEA accepted for filing the Zevalin Marketing Authorization Application, or MAA, submitted by Schering AG in the European Union. In March 2002, the "Summary of Product Characteristics" was approved by the European Committee for Proprietary Medicinal Products, or CPMP, for the treatment of adult patients with Rituximab relapsed or refractory CD20+ follicular B-cell NHL. The CPMP's final approval is pending approval by the EMEA of our manufacturing facilities and fill/finish provider.

We also have four other antibodies in various stages of clinical development for treatment of autoimmune diseases and cancer:

- PRIMATIZED Anti-CD23 (IDEC-152) is being developed as a treatment for allergic asthma and allergic rhinitis as well as chronic lymphocytic leukemia (CLL). We completed a 30-patient Phase I clinical trial with IDEC-152 in allergic asthma that demonstrated a favorable safety profile. We initiated a Phase I/II study in allergic asthma in February 2002 and a Phase II pilot study in patients with seasonal allergic rhinitis in June 2002. In March 2003, data from the Phase II pilot study in allergic rhinitis was presented, demonstrating that IDEC-152 was safe and well tolerated. Treatment resulted in a notable reduction in total and allergen specific IgE levels, however, no significant effect on clinical symptom scores was observed. In September 2002, we initiated a Phase I study in CLL.
- PRIMATIZED® Anti-CD80 (Anti-B7.1) (IDEC-114) is being developed as a treatment for NHL and may also find application in various autoimmune diseases. In February 2002, we initiated a Phase I/II clinical trial with IDEC-114 in patients with relapsed or refractory follicular lymphoma. In December 2002, we announced interim results from this study showing that IDEC-114 was well tolerated and responses were observed in patients treated with the higher doses. In December 2002, we initiated an additional Phase I/II clinical trial with IDEC-114 in combination with Rituxan in patients with relapsed or refractory follicular lymphoma. In September 2002, we announced the results of our two Phase II clinical trials with IDEC-114 for patients with moderate-to-severe psoriasis, and that the data did not support further development in this indication.
- PRIMATIZED Anti-CD4 (IDEC-151) has been examined as a treatment for rheumatoid arthritis. A Phase II trial of this antibody was initiated in
  August 2000 in combination with methotrexate in patients with moderate to severe rheumatoid arthritis. The trial was completed in 2002. Based
  upon initial results of a Phase II study of Rituxan in rheumatoid arthritis by

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Roche that suggests Rituxan has significant activity in rheumatoid arthritis, we have decided to focus on Rituxan as a treatment for rheumatoid arthritis instead of IDEC-151. IDEC-151 is being considered for development in various other autoimmune diseases.

• Humanized Anti-CD40L (IDEC-131) is being developed as a treatment for autoimmune diseases. In 2001, we initiated three separate Phase II clinical trials with IDEC-131 in three different autoimmune indications, immune thrombocytopenic purpura, or ITP, psoriasis and Crohn's disease.

In June 2002, all clinical trials of IDEC-131 were placed on clinical hold due to the occurrence of a possible safety signal related to thromboembolism. We are currently working with the FDA to remove the clinical hold status.

We have two other products in clinical development for treatment of cancer:

- IDEC-160 is an in-licensed, orally administered small-molecule, which is being initially developed by Nippon Shinyaku Co., Ltd., or Shinyaku, as a treatment for solid cancers. Shinyaku has initiated Phase I trials in patients with solid tumors.
- IDEC-201 is an in-licensed interferon beta gene delivery system using an adenovirus vector. We will complete an ongoing Phase I/II trial in patients with glial tumors that was begun by our licensor, Biogen, Inc., or Biogen. Biogen has future rights to participate in development and commercialization of IDEC-201.

## Therapeutic Antibodies and the Immune System

The immune system is composed of specialized cells, including B cells and T cells, that function in the recognition, destruction and elimination of disease-causing foreign substances and virally infected or malignant cells. The role of these specialized cells is determined by receptors on the cell surface that govern the interaction of the cell with foreign substances and with the rest of the immune system. For example, each differentiated B cell of the immune system has a different antibody anchored to its surface that serves as a receptor to recognize foreign substances. This antibody then triggers the production of additional antibodies that, as circulating molecules, bind to and eliminate these foreign substances. Each foreign substance, such as tumor cell, virus or bacteria, is individually identifiable by structures on its surface known as antigens, which serve as binding sites for the specific antibodies. T cells play more diverse roles, including the identification and destruction of virally infected or malignant cells.

A variety of technologies have been developed to produce antibodies as therapeutic agents. These include hybridoma technology and molecular biology techniques such as gene cloning and expression, which can now be applied to the generation, selection and production of hybrid monoclonal antibody varieties known as chimeric and humanized antibodies, as well as strictly human antibodies. Chimeric antibodies are constructed by combining portions of non-human species, typically mouse antibodies, with human antibodies. In these applications, the portion of the antibody responsible for antigen binding, which we refer to as the variable region, is taken from a non-human antibody and the remainder of the antibody, which we refer to as the constant region, is taken from a human antibody. Compared to mouse-derived monoclonal antibodies, chimeric antibodies generally exhibit lower immunogenicity, which is the tendency to trigger an often adverse immune response such as a human anti-mouse antibody, or HAMA response. Chimeric antibodies are also cleared more slowly from the body and function more naturally in the human immune system. Humanized antibodies can be constructed by grafting several small pieces of a murine antibody's variable region onto a constant region framework provided by a human antibody. This process, known as CDR-grafting, reduces the amount of foreign materials in the antibody, rendering it closer to a human antibody. However, the construction of humanized antibodies by CDR-grafting requires complex computer modeling, and the properties of the resulting antibody are not completely predictable and may, in fact, still trigger a HAMA response.

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All human cells express a broad variety of surface antigens which are cell surface markers and can be used to differentiate one cell type from another. Monoclonal antibodies may be used to bind to specific subsets of human cells and may act to deplete, to suppress or to up-regulate the activity of the targeted cells. Indeed, the high specificity of monoclonal antibodies enables them to selectively act against many different types of cells, including cells involved in the immune response (B cells and T cells), other normal cell types which may be involved in disease such as macrophages, neutrophils and endothelial cells, or specific tumor cells. Depletion of diseased cells or suppression of disease-causing activities may be possible by using antibodies that attach to specific antigens on the surface of target cells. Monoclonal antibodies may also be used to bind to molecules, for example, cytokines, which serve as soluble mediators of immune system cell activity. By neutralizing these molecules, monoclonal antibodies may be used to alter immune cell activity or cell migration, which exists in many inflammatory conditions.

## **Diseases of the Immune System**

As with other cell types in the body, B cells and T cells may become malignant and develop into immune system tumors, such as B-cell NHLs. B-cell NHLs are cancers of the immune system that currently afflict approximately 300,000 patients in the United States. Treatment alternatives for B-cell NHL patients include chemotherapy, radiation therapy and, more recently, Rituxan and Zevalin. Rituxan is approved for use in low grade or follicular, relapsed or refractory CD20-positive B-cell NHL. Zevalin is approved for use in relapsed or refractory low grade, follicular, or transformed B-cell NHL, including patients with Rituxan refractory follicular NHL. B-cell NHLs are diverse with respect to prognosis and treatment, and are generally classified into one of three groups (low, intermediate or high grade) based on histology and clinical features. We estimate that approximately half of the 300,000 patients afflicted with B-cell NHL in the United States have low grade or follicular disease. Patients with low grade lymphomas have a fairly long life expectancy from the time of diagnosis, with a median survival of 6.6 years, despite the fact that low grade NHLs are almost always incurable. Intermediate and high grade lymphomas are more rapidly growing forms of these cancers which, in some cases, may be curable with early, aggressive chemotherapy. New diagnoses of NHLs in the United States are estimated to be 53,400 in 2003. In the United States, more than 85% of all non-Hodgkin's lymphomas are of B-cell origin; the remainder are of T-cell origin.

Owing to the fluid nature of the immune system, low grade B-cell lymphomas are usually widely disseminated and characterized by multiple tumors at various sites throughout the body upon first presentation. Treatment courses with chemotherapy or radiation therapy often result in a limited number of remissions for patients with low grade B-cell lymphomas. The majority of patients in remission will relapse and ultimately die either from their cancer or from complications of conventional therapy. Fewer patients achieve additional remissions following relapse and those remissions are generally of shorter duration as the tumors become increasingly resistant to subsequent courses of chemotherapy. Therapeutic product development efforts for these cancers have focused on both improving treatment results and minimizing the toxicities associated with standard treatment regimens. Immunotherapies with manageable toxicity and demonstrated efficacy, such as Rituxan and Zevalin, might be expected to reduce treatment and hospitalization costs associated with side effects or opportunistic infections, which can result from the use of chemotherapy.

Psoriasis, inflammatory bowel disease, or IBD, asthma, allergic rhinitis, rheumatoid arthritis, systemic lupus erythematosus, or SLE, ITP and multiple sclerosis, or MS, are autoimmune or inflammatory diseases that require ongoing therapy and afflict millions of patients in the United States. Autoimmune disease occurs when the patient's immune system goes awry, initiating a cascade of events that results in an attack by the patient's immune system against otherwise healthy tissue and often includes inflammation of the involved tissue. Autoimmune diseases have typically been treated with products such as immunosuppressive agents and corticosteroids. These therapies are limited for several

reasons, including their lack of specificity and side effect profiles. Despite recent approvals of targeted biologic therapies there remains a significant need for safe and effective agents to treat these debilitating diseases.

#### **Technology**

We develop products for the management of immune system cancers and autoimmune and inflammatory diseases. Our antibody products bind to specific subsets of human immune system cells or to soluble mediators of immune cell activity, and act to deplete or to alter the activity of these cells. The products are administered intravenously and target cells or soluble mediators located in easily accessible compartments of the body, specifically the blood, the lymphatic fluid and the synovial fluid. For treatment of B-cell NHLs, our products target a cell surface marker known as CD20 which is present only on B cells but not on B-cell precursors. These products act to reduce total B-cell levels, including both malignant and normal B cells. The depletion of normal B cells observed in clinical experience to date has been only temporary, with regeneration occurring within months from the unaffected B-cell precursors. We believe that Rituxan provides therapeutic alternatives and can complement certain existing treatments of various B-cell NHLs. We also believe that our radioimmunotherapeutic agent, Zevalin, will provide an additional alternative for the treatment of certain B-cell NHLs.

Due to their specificity and affinity for cell surface receptors, monoclonal antibodies are an attractive means by which to treat autoimmune diseases. Attachment of monoclonal antibodies to specific cell surface receptors can be used to suppress aberrant and unwanted immune activity. Historically, however, the use of monoclonal antibodies as an ongoing therapy has been limited by the body's rejection of the murine components of the antibodies. Murine monoclonal antibodies, which are structurally different from human antibodies, tend to trigger adverse immune reactions when used as therapies. These reactions include a HAMA response in which the patient's immune system produces antibodies against the therapeutic antibody, thus limiting its effectiveness.

We have developed the following proprietary technologies for use with and in the development of our products:

• PRIMATIZED Antibody Technology. We have developed a proprietary PRIMATIZED antibody technology designed to avoid HAMA responses and other immunogenicity problems by developing monoclonal antibodies from primate rather than mouse B cells. These antibodies are characterized by their strong similarity to human antibodies and by the absence of mouse components. In 1998, we were issued a U.S. patent covering our PRIMATIZED antibodies. Underlying this proprietary technology is our discovery that macaque monkeys produce antibodies that are structurally indistinguishable from human antibodies in their variable (antigen-binding) regions. Further, we found that the macaque monkey can be immunized to make antibodies that react with human, but not with macaque, antigens. Genetic engineering techniques are then used to isolate the portions of the macaque antibody gene that encode the variable region from a macaque B cell. This genetic material is combined with constant region genetic material from a human B cell and inserted into a host cell line which then expresses the desired antibody specific to the given antigen. The result is a part-human, part-macaque PRIMATIZED antibody which appears structurally to be so similar to human antibodies that it may be accepted by the patient's immune system as "self." This development allows the possibility of therapeutic intervention in chronic diseases or other conditions that are not amenable to treatment with antibodies containing mouse components. Our objective with our PRIMATIZED antibodies is to provide therapies that can be used to control chronic autoimmune diseases characterized by overactive immune functions. We are currently using our PRIMATIZED technology for the development of our IDEC-151, IDEC-152 and IDEC-114 product candidates

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- *PROVAX*<sup>TM</sup> *Antigen Formulation.* We have also discovered a proprietary antigen formulation, PROVAX, which has shown the ability to induce cellular immunity, manifested by cytotoxic T lymphocytes, in animals immunized with protein antigens. Cellular immunity is a counterpart to antibody-based immunity and is responsible for the direct destruction of virally infected and malignant cells. PROVAX is a combination of defined chemical entities and may provide a practical means for the development of effective immunotherapies that act through the induction of both antibody and cell-mediated immunity. We believe these immunotherapies may be useful for the treatment of various cancers and viral diseases
- *Proprietary Vector Technologies*. We have developed methods of engineering mammalian cell cultures using proprietary gene expression technologies, or vector technologies that rapidly and reproducibly select for stable cells, producing high levels of desired proteins. These technologies allow the efficient production of proteins at yields that are competitive with current commercial cell culture manufacturing methods. We have successfully applied one of these technologies to the commercial scale production of Rituxan.

## **Our Products and Product Candidates**

Rituxan, our first product, and Zevalin, our second product approved for marketing in the United States, as well as our other primary products under development, address immune system disorders, such as lymphomas and autoimmune and inflammatory diseases. In addition, we have discovered other product candidates through the application of our technology platform. The products either commercialized or in clinical development by our partners and us are described in the following table.

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We have retained exclusive marketing rights in the United States for all of our products except Rituxan.

	Indication	Status	Development/Marketing Partners
Rituxan	Certain B-cell NHLs	U.S., Canada, European Union, and Japan: Approved	Genentech (U.S. copromotion) Roche (worldwide except U.S. and Japan) Zenyaku and Roche (Japan)
	Rheumatoid arthritis	Phase II; beginning implementation of Phase III	Genentech (U.S. copromotion) Roche (worldwide except U.S.)

Zevalin	Certain B-cell NHLs (radioimmunotherapy)	U.S.: Approved European Union: MAA accepted for filing	Schering AG (worldwide except U.S.)
PRIMATIZED Anti-CD23 (IDEC-152)	Allergic asthma and allergic rhinitis	Phase I/II	Seikagaku Corporation (worldwide except North, Central and South America)
	CLL	Phase I	Seikagaku Corporation (worldwide except North, Central and South America)
PRIMATIZED Anti-CD80 (Anti-B7.1) (IDEC-114)	NHL and various autoimmune diseases	Phase I/II	Mitsubishi Pharma Corporation (Asia)
PRIMATIZED Anti-CD4 (IDEC- 151) (Clenoliximab)	Various autoimmune diseases	Phase II	IDEC has worldwide rights
Humanized Anti-CD40L (IDEC-131)	Various autoimmune diseases	Phase II (on hold)	Eisai Co., Ltd. (Europe and Asia)
IDEC-160	Solid tumors	Phase I	Shinyaku (Asia)
IDEC-201	Glioma	Phase I/II	Biogen and IDEC share worldwide rights

#### Rituxan

Rituxan is a genetically engineered, chimeric murine/human monoclonal antibody designed to harness the patient's own immune mechanisms to destroy normal and malignant B cells. In November 1997, Rituxan was approved in the United States for treatment of various B-cell NHLs. We market Rituxan in the United States with Genentech under a copromotion arrangement. Roche sells rituximab outside the United States, except in Japan where it copromotes Rituxan in collaboration with Zenyaku. Outside the United States, Canada and Japan, rituximab is marketed as MabThera.

Our laboratory studies show that the Rituxan antibody binds to the CD20 antigen on B cells and activates a group of proteins known as complement, leading to normal and malignant B-cell destruction. Additionally, we believe that the Rituxan antibody, when bound to the CD20 antigen, recruits macrophages and natural killer cells to attack the B cells. Rituxan can also directly induce apoptosis or programmed cell death. Through these and other mechanisms, the antibody utilizes the body's immune defenses to lyse, or rupture, and deplete B cells. B cells have the capacity to regenerate from early precursor cells that do not express the CD20 antigen. The depletion of normal B cells observed in clinical experience to date has been only temporary, with normal B-cell regeneration back to baseline levels typically occurring within nine to twelve months.

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#### Rituxan in Malignant Diseases

Rituxan was the first monoclonal antibody approved in the United States for a cancer therapy indication. Rituxan is unique in the treatment of B-cell NHLs due to its specificity for the antigen CD20, which is expressed only on normal and malignant B cells and not on precursor B cells or other tissues of the body. Rituxan's mechanism of action utilizes the body's own immune system as compared to conventional lymphoma therapies, including experimental radioimmunotherapies. These properties of Rituxan also allow its use in patients where chemotherapy is either poorly tolerated or ineffective in inducing disease remissions. Rituxan is easily administered as outpatient therapy by personnel trained in the use of chemotherapies. A standard course of Rituxan therapy consists of four intravenous infusions given on days one, eight, 15 and 22, whereas chemotherapy is given typically in repeating cycles for up to four to eight months. In May 2001, the FDA approved our sBLA relating to the use of Rituxan in expanded dosing, including retreatment, times eight dosing for the treatment of B-cell NHL, including bulky disease. The sBLA also amended our package insert to update safety information. In addition, a Dear Healthcare Provider letter was sent to physicians to enhance their understanding of adverse events that may be associated with Rituxan use.

Rituxan is indicated for single agent use in relapsed or refractory, low grade or follicular CD20-positive B-cell NHLs, which comprise approximately half of the B-cell NHLs in the United States. Ongoing or completed Phase II studies suggest that Rituxan may also be useful in combination with chemotherapy in low grade or follicular, relapsed or refractory, CD20-positive B-cell NHLs, and as a single agent or in combination with various chemotherapies in the treatment of other forms of B-cell NHLs and chronic lymphocytic leukemia, or CLL. In relapsed or chemotherapy-refractory low grade B-cell NHLs, which to date have proven to be incurable, Rituxan provides a means to induce remissions of disease in some patients without subjecting the patient to the toxicity and duration of therapy that are typical of chemotherapy regimens.

In a Phase III clinical trial, Rituxan, given as a single agent to patients with relapsed or refractory, low grade or follicular CD20-positive B-cell NHL, induced partial or complete responses to therapy (using the response criteria as defined in the IDEC protocol) of 48% of patients on an intent-to-treat basis, which represented 80 of 166 patients. Of the 80 responding patients, tumor shrinkage greater than 50% was verified over at least two independent observations 28 days apart; 10 were complete responses, or 6%, and 70 were partial responses, or 42%. The median duration of response, which is the time from response onset to first determination of tumor regrowth, in the 80 responders was 11.6 months. Retrospective analysis of patient subgroups in the Phase III Rituxan trial showed responses in patients with poor prognostic features, and who generally respond poorly to chemotherapy regimes, such as age greater than 60, extranodal disease, prior relapse from autologous bone marrow transplant, or relapse or failure of anthracycline-containing regimens. In newly diagnosed aggressive B-cell NHLs, termed Diffuse Large Cell Lymphoma, a study has demonstrated significantly improved response rates, complete response rates, disease free survival and overall survival with the addition of Rituxan to combination chemotherapy.

There are standard response criteria for solid tumor cancers, CLL, Hodgkin's disease and acute myelogenous leukemia, but until recently, none for B-cell NHL. As a result, clinical response rates in B-cell NHL may vary depending on which criterion is being applied. One of the protocol-defined requirements for scoring a complete response in the Rituxan pivotal trial was that all measurable lesions shrink to less than 1x1cm. Using this conservative criterion, we reported an overall response rate of 48% with a 6% complete response rate, referred to as a CR rate. Based on a paper published by Cheson, *et al.* in the *Journal of Clinical Oncology*, the lymphoma experts have now standardized the response criteria in NHL. Prior to the Cheson paper and the subsequent standardization, our protocol definition of overall response rate and complete response rates were based on our investigators and our own criteria. Exploratory analysis applying the new International Workshop NHL Response Criterion

Standards for NHL to our Rituxan Phase III trial shows an overall response rate of 56% with a CR rate of 32%.

In December 1999, we announced updated information on the results of a Phase II Rituxan retreatment study presented at the American Society of Hematology Conference, or ASH conference. This Phase II study in patients with low grade or follicular, CD20-positive B-cell NHL was conducted to determine the safety and efficacy of Rituxan in patients who had relapsed or were refractory to prior chemotherapy, but had responded previously to Rituxan. From the analyses of the study, patients who responded to one regimen of Rituxan may be retreated with additional courses of Rituxan without impairment of bone marrow function, or myelosuppression, or development of an immune response, or antibodies, to chimeric antibody therapy, a response called human anti-chimeric antibody, or HACA. Of 60 patients treated, 57 were considered evaluable for efficacy. The overall response rate using our protocol was 40%, with 6 out of 57, or 11%, achieving complete responses and 17 out of 57, or 30%, achieving partial responses. The overall safety profile seen with retreatment was similar to what was reported for the initial treatment with Rituxan.

The most common adverse events associated with Rituxan, based on our clinical trial experience, are infusion-related, consisting mainly of mild to moderate flu-like symptoms, for example, fever, chills and rigors, that occur in the majority of patients during the first infusion. Other events which occur with less frequency include nausea, rashes, fatigue and headaches. More serious events include hypotension, wheezing, tumor lysis syndrome, rare pulmonary events including pneumonitis and bronchiolitis obliterans, mucocutaneous reactions, angina or arrhythmia. Though infusion related symptoms are usually limited in duration to the period of infusion and decrease with subsequent infusions, rare serious infusion and non-infusion events have resulted in fatalities.

In an effort to identify expanded applications for Rituxan, we, in conjunction with Genentech and Roche, have supported several Rituxan post-marketing trials including:

- combination therapy with chemotherapy regimens for both low grade and intermediate/high grade NHL;
- single agent therapy in newly diagnosed, previously untreated low grade NHL;
- integration into autologous bone marrow transplant regimens both as an in vivo purging agent prior to bone marrow harvest and post-transplant as consolidation therapy; and
- treatment of AIDS-related B-cell NHLs.

Additionally, clinical trials are ongoing in other B-cell malignancies such as CLL and lymphoproliferative disorders associated with solid organ transplant therapies.

#### Rituxan with CHOP Chemotherapy and Rituxan Maintenance

At the ASH conference in December 2000, a Rituxan presentation was given during the plenary session based on the Coiffier *et al.* study entitled "MabThera (Rituximab or Rituxan) plus CHOP is superior to CHOP Alone in Elderly Patients with Diffuse Large B-Cell Lymphoma: Interim Results of a Randomized GELA Trial." At the ASH conference in December 2001, results were presented on all 400 previously untreated elderly patients randomized into two arms of the study comparing standard CHOP, a common chemotherapy regimen consisting of cyclophosphamide, doxorubicin, vincristine and prednisone, given every three weeks for eight cycles, versus standard CHOP, with Rituxan given day one of each cycle of CHOP. This data was also published in the *New England Journal of Medicine* in January 2002.

After a median follow-up of two years, Coiffier *et al.* found a significant improvement in event-free survival for the Rituxan plus CHOP arm versus the CHOP alone treated arm (57% versus 37%, respectively). Event-free survival was defined as ongoing survival without events including disease

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progression or relapse, death or initiation of new alternative treatment. Overall survival was increased from 57% in the CHOP alone arm to 70% in the Rituxan plus CHOP arm. Complete response rate (disappearance of all detectable signs of cancer) increased from 63% in the CHOP alone arm to 76% in the Rituxan plus CHOP arm.

Approximately 10% of patients in the Rituxan plus CHOP arm experienced Grade 3/4 infusion-related events. As seen in prior studies with Rituxan, these events were generally limited to the first infusion of Rituxan and were reversible.

In December 2001, we announced updated information on the results of a Phase II study assessing the safety and effectiveness of Rituxan used in combination with CHOP chemotherapy, in low grade or follicular B-cell NHL. The overall response rate using the IDEC protocol, in the Phase II study was 100% in 35 evaluable patients with 22 patients, or 63%, achieving complete responses and 13 patients, or 37%, achieving partial responses. The median duration of response was 63.6+ months with progression-free survival not reached after a median observation time of 65.1+ months. Twenty-one patients, or 60%, are still in remission beyond 46+ months and up to 86.3+ months.

Dr. John Hainsworth reported in the *Journal of Clinical Oncology* in 2002 results of a study he and colleagues conducted using Rituxan monotherapy with maintenance in patients with newly diagnosed low grade NHL. A total of 62 patients were enrolled, and 60 patients completed an initial four-week course of Rituxan and were assessable for response. Patients with stable disease or response went on to receive additional four-week courses of Rituxan every six months for two years. The overall response rate after initial therapy was 47%, which increased to 73% with 37% complete responses. The median progression-free survival was 34 months. Furthermore, the investigators noted that there was no apparent cumulative or additional toxicities seen with the maintenance therapy.

Swiss investigators conducted a randomized trial in patients with newly diagnosed or relapsed indolent NHL. Patients who achieved a response or stable disease after an initial standard course of Rituxan were randomized to either observation or additional Rituxan maintenance, administered on a schedule of a single dose every two months for a total of four additional doses. Two hundred patients were enrolled, and 151 patients were eligible for randomization. Results of the study were updated at the 2002 ASH conference. The median time to treatment failure in newly diagnosed patients was 36 months compared to 18.4 months for the maintenance arm compared to observation. In relapsed patients, the median time to treatment failure was 14 months compared to 11 months.

A large, randomized controlled cooperative Phase III trial by the National Cancer Institute, the Eastern Cooperative Oncology Group, the Cancer and Leukemia Group B and the Southwest Oncology Group is examining whether the addition of Rituxan administered on a maintenance regimen (four infusions every six months for two years) to the CHOP or CHOP/Rituxan responders will improve cure rates, or long-term remission, in individuals over the age of 60 years with intermediate/high grade B-cell NHL. Enrollment on this trial was completed in July 2001, with 632 patients accrued. Initial results may be presented at the 2003 ASH conference.

#### Rituxan in Autoimmune Diseases

In 2001, Stasi *et al.* published data on the use of Rituxan in patients with chronic ITP. Of the 25 patients treated, an overall response rate of 52% was observed, with 20% of patients achieving a complete response (defined as a platelet count of greater than 100,000). Seven patients (28%) had sustained responses of six months or longer.

Two abstracts presented at the ASH conference in December 2001 also explored the safety and efficacy of Rituxan in patients with ITP. A Phase I/II evaluated ITP patients who had failed corticosteroid therapy and had platelet counts less than 75,000. Of all 20 patients enrolled, 25% responded with duration of five to 11 months. Of the ten post-spenectomy patients, 40% responded.

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Response was defined as platelet counts greater than 100,000 (Saleh *et al*). Another Phase II study enrolled 21 patients of which 14 were followed for greater than 10 weeks. Of these 14 patients, 57% responded, with a 45% response rate among the 11 patients who were post-splenectomy. Response was defined as a platelet count greater than 50,000. First infusion-related events were experienced by eight of 21 patients (Cooper *et al*).

At the American College of Rheumatology Meeting in 2000, Edwards *et al.* presented results of a small open label study that evaluated the impact of B-lymphocyte depletion produced by Rituxan in patients with erosive rheumatoid arthritis. The authors concluded that B-cell depletion showed promise as a safe and effective therapy for rheumatoid arthritis. Initial results of a Roche sponsored Phase II blinded, randomized, controlled study of Rituxan alone or in combination with methotrexate or cyclophosphamide in rheumatoid arthritis were presented at the American College of Rheumatology Meeting in 2002. These results suggest that Rituxan had significant activity in rheumatoid arthritis. We, in conjunction with Genentech and Roche, are now pursuing Phase III trials and additional Phase II trials in this indication.

## Zevalin

Due to the sensitivity of B-cell tumors to radiation, radiation therapy has historically played, and continues to play, an important role in the management of B-cell lymphomas. Radiation therapy currently consists of external beam radiation focused on isolated areas of the body or areas with high tumor burden and, more recently, the Zevalin therapeutic regimen. Zevalin, our radioimmunotherapy product approved for treatment of certain B-cell NHL, delivers targeted immunotherapy by means of injectable radiation to target sites expressing the CD20 antigen, such as lymphatic B-cell tumors. The Zevalin therapeutic regimen is sold as one product and consists of two kits: an imaging kit for use with indium-111 and a therapeutic kit for use with yttrium-90.

In clinical testing, the Zevalin antibody, which is the murine parent of Rituxan, radiolabeled with the isotope indium-111 was used to estimate the radiation absorbed dose to normal organs from the subsequently administered therapeutic product, which uses the isotope yttrium-90. The gamma emission of the indium is detectable outside the body, thereby allowing the physician to determine the biodistribution of the antibody in the patient. The companion yttrium-90 isotope provides targeted radiation therapy by emitting a high-energy beta particle that is absorbed by surrounding tumors, leading to tumor destruction. Our objective with Zevalin is to provide an effective, systemic radioimmunotherapy in an outpatient setting.

The Zevalin therapeutic regimen includes two doses of Rituxan one week apart, to deplete peripheral blood B cells and improve Zevalin biodistribution. The first dose of Rituxan is followed by indium-111-Zevalin. Gamma camera images are then obtained at two to 24 hours, 48 to 72 hours, and an optional image at 90 to 120 hours. These images are obtained to confirm expected biodistribution. If acceptable biodistribution is demonstrated, the second dose of Rituxan is followed by yttrium-90-Zevalin. Yttrium-90, which is supplied by MDS Canada Inc., formerly MDS Nordion Inc., or MDS Canada, is attached to the antibody at the radiopharmacy just prior to the therapeutic infusion in the patient. The entire regimen, therefore, can be completed on an outpatient basis in approximately one week.

Other radioisotopes, such as iodine-131, emit both beta and gamma radiation and, depending on state and institutional regulations, may require that the patient be hospitalized and isolated in a lead-shielded room for several days. If administered as an outpatient therapy, extensive radiation safety precautions are necessary to limit radiation exposure to family members and the general public. In contrast, the beta particle emitted by yttrium-90 is absorbed by tissue immediately adjacent to the antibody and is concentrated at the antibody target. This short penetrating radiation supports the use of Zevalin in outpatient therapy with minimal radiation precautions for the patient.

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As the basis for our BLA approved by the FDA on February 19, 2002, we completed two multi-center pivotal Phase III studies of Zevalin in the treatment of relapsed or refractory, low grade, follicular or CD20-positive transformed B-cell NHL.

Final results for these two studies were published in the *Journal of Clinical Oncology* in 2002. The first, randomized controlled study conducted compares Zevalin plus Rituxan, to Rituxan alone in 143 patients with relapsed or refractory, low grade, follicular or transformed CD20-positive B-cell NHL. Patients receiving Zevalin plus Rituxan showed an overall response rate of 80%, compared to an overall response rate of 56% in patients receiving Rituxan alone. Fifty-six percent of patients enrolled in the study were refractory to their last course of chemotherapy, *i.e.*, they did not achieve a response or had a time to progression of less than six months with their most recent course of chemotherapy. Thirty-four percent of the Zevalin patients achieved complete responses to therapy, compared to 20% of Rituxan patients. The median time to progression for all patients in the Zevalin arm versus the Rituxan arm was 10.6 months and 10.1 months, respectively. The median time to progression in patients with follicular NHL, which represents the majority of patients, was 15.0 months versus 10.2 months, respectively. Finally median time to progression in patients who achieved a complete response was 24.7 months versus 13.2 months, respectively. Thirty-six percent of the patients on the Zevalin arm who attained a complete response remain in remission at three to four years following treatment.

The second pivotal study evaluated the safety and efficacy of Zevalin in follicular NHL patients who are refractory to Rituxan, *i.e.*, who did not achieve a response or had a time to progression of less than six months with their most recent course of Rituxan. Under the new International Workshop NHL Response Criterion Standards for NHL, the overall response rate was 74% who responded to treatment with Zevalin, with 15% of those individuals achieving a complete response to therapy. Seventy-four percent of these patients had sizable tumors (greater than 5cm in single diameter) and 82% were chemotherapy-resistant to at least one prior chemotherapy treatment. The dosimetry results obtained in the second Phase III trial concluded that the Zevalin biodistribution and estimated radiation absorbed dose to normal body organs were not affected by prior treatment with Rituxan.

In both studies, toxicity associated with Zevalin treatment was primarily reductions in blood-cell counts. Patients with impaired bone marrow reserve, as indicated by lower baseline platelet counts, or evidence of significant bone marrow damage from prior therapy, as well as patients with greater involvement of the bone marrow with lymphoma, were more likely to experience such toxicity. Decreased blood counts resulted in hospitalizations for infection in 7% of patients and life-threatening bleeding in less than 1%. Approximately 50% of patients experience generally mild, reversible infusion reactions, such as chills, fever, throat irritation and nausea, with a lower incidence on the second treatment day. These reactions are consistent with those seen with Rituximab therapy as single-agent therapy and the incidence of infusion reactions was similar between the two arms in the randomized trial.

Additional areas of investigation include repeated treatment with Zevalin, as well as, incorporation into high-dose treatment strategies that employ autologous stem cell rescue. Investigators at the Mayo Clinic in Rochester, MN are evaluating whether planned Zevalin retreatment is feasible and potentially efficacious. Preliminary results were presented at the 2002 ASH conference. In addition, separate investigators at the City of Hope in Duarte, CA; Northwestern University in Chicago, IL and the Mayo Clinic presented data from Phase I trials that high doses of Zevalin could be administered safely in combination with chemotherapy as part of a myeloablative stem cell transplantation program. These interim results were also presented at the 2002 ASH conference.

We expect that Rituxan and Zevalin will become complementary products for the management of B-cell NHLs. Most B-cell NHLs are treated today in community-based group practices. Rituxan fits nicely into the community practice, as no special equipment, training or licensing is required for its administration or for management of treatment-related side effects. Rituxan has shown activity even in

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patients refractory to chemotherapy and is indicated for this use, so that it provides a viable option for the community-based oncologist prior to referral of the patient to a medical center for treatment with the more aggressive therapy, Zevalin. By contrast, all radioimmunotherapies will be administered by nuclear medicine specialists or radiation oncologists at medical or cancer centers that are equipped for the handling, administration and disposal of radioisotopes. Also, the nuclear medicine department, but not the community-based practice, has the specialized equipment and governmental licenses that are required for use of radioisotopes.

We believe that referral patterns will develop for treatment of B-cell NHL patients with radioimmunotherapies at medical centers after initial treatment options, such as Rituxan or frontline chemotherapy, are no longer effective. This trend is further reinforced by the observation made by us, and by others working in the field, of the substantial clinical activity of radioimmunotherapies in patients with relapse disease. Thus Zevalin is positioned as a complementary product to Rituxan used throughout the course of a patient's disease, providing an alternative for both the patient and the healthcare professional to conventional chemotherapies.

## PRIMATIZED Anti-CD23 (IDEC-152)

In December 1994, we entered into a collaboration with Seikagaku Corporation, or Seikagaku, aimed at the development of PRIMATIZED anti-CD23 antibodies for the potential treatment of allergic rhinitis, allergic asthma and other allergic conditions. Antibodies against the CD23 receptor on various white blood cells inhibit the production of immune system molecules called immunoglobulin class E, or IgE, which are known to trigger allergic conditions. At the same time, anti-CD23 antibodies do not affect the production of other immunoglobulins, which are the patient's own antibodies responsible for granting protective immunity to infectious agents. Thus, PRIMATIZED anti-CD23 antibodies may provide a unique new approach to treating chronic illnesses such as allergic rhinitis and allergic asthma. This effort has resulted in the identification of a PRIMATIZED antibody lead candidate, IDEC-152, which underwent preclinical testing, process development and manufacturing of clinical material during 1999. We filed an Investigational New Drug Application, or IND, for IDEC-152 in November 1999 and began a Phase I clinical trial in allergic asthma in February 2000 to evaluate its safety, tolerability and pharmacokinetics. In March 2001 the results of the Phase I trial were presented at the American Academy of Allergy Asthma and Immunology. A total of 30 patients entered the trial with 24 receiving IDEC-152 and six receiving a placebo. The safety trial was favorable, with adverse events in patients who received IDEC-152 being very similar to those of placebo patients. Substantial prolonged reductions in IgE levels were noted in IDEC-152 patients. Based on the results of this trial, a Phase I/II trial in allergic asthma and a Phase II pilot study in seasonal allergic rhinitis have been initiated. In March 2003, data from the Phase II pilot study in allergic rhinitis was presented, demonstrating that IDEC-152 was safe and well tolerated. Treatment resulted in a notable reduction in total and allergen specific IgE levels, however,

## PRIMATIZED Anti-CD80 (Anti-B7.1) (IDEC-114)

The CD80 antigen is expressed on the surface of follicular and other lymphoma cells. Preclinical studies have demonstrated that IDEC-114 has antitumor activity against lymphoma cell lines that express CD80. Based on these results, in February 2002, we initiated a Phase I/II clinical trial to evaluate the safety, efficacy, and pharmacokinetics of multiple doses of IDEC-114 in patients with relapsed or refractory follicular lymphoma. In December 2002, we announced interim results from this study showing that IDEC-114 was well tolerated and responses were observed in patients treated with the higher doses. Additionally, in December 2002, we initiated a Phase I/II clinical trial with IDEC-114 in combination with Rituxan to evaluate the safety, efficacy, and pharmacokinetics of multiple doses of

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IDEC-114 administered in combination with Rituxan in patients with relapsed or refractory follicular lymphoma.

In September 2001, we entered into an extension of our research and development collaboration with Mitsubishi Pharma Corporation, or Mitsubishi, formerly Mitsubishi-Tokyo Pharmaceuticals, Inc., which focuses on the development of PRIMATIZED antibodies directed at the CD80 antigen. The CD80 antigen appears on the surface of antigen-presenting cells and is involved in the interaction of these cells with T cells in triggering a cascade of immune system

responses. Antibodies directed at the CD80 antigens may block this cascade and, therefore, may be useful in preventing unwanted immune responses in various inflammatory and chronic autoimmune conditions such as psoriasis and MS. We have completed four studies of IDEC-114 in psoriasis. Based on the favorable results of the Phase I and Phase I/II studies, in 2001 we initiated two Phase II clinical trials with IDEC-114 in patients with moderate to severe psoriasis. In September 2002, we announced the results of our two Phase II psoriasis clinical trials with IDEC-114 and that the results did not support further development in this indication. Studies in other autoimmune indications are being considered.

#### PRIMATIZED Anti-CD4 (IDEC-151)

IDEC-151 was selected as our lead PRIMATIZED anti-CD4 antibody for the treatment of rheumatoid arthritis. In a Phase I portion of a Phase I/II study of 32 patients with moderate to severe rheumatoid arthritis, the results of which were announced in late November 1997, IDEC-151 displayed no CD4 cell depletion and no infusion-related adverse events. Under the terms of an agreement with GlaxoSmithKline, we are obligated to pay GlaxoSmithKline royalties on sales by us, our affiliates and licensees on certain PRIMATIZED anti-CD4 products. In August 2000, we initiated a Phase II trial of this antibody in combination with methotrexate in patients with moderate to severe rheumatoid arthritis. This trial was completed in 2002. Based upon initial results of a Phase II study of Rituxan in rheumatoid arthritis by Roche that suggests Rituxan has significant activity in rheumatoid arthritis, we have decided to focus on Rituxan as a treatment for rheumatoid arthritis instead of IDEC-151. IDEC-151 is being considered for development in various other autoimmune diseases.

#### Humanized Anti-CD40L (IDEC-131)

In December 1995, we entered into a research and development collaborative agreement with Eisai Co., Ltd., or Eisai. The collaboration focuses on developing a humanized antibody against the CD40 ligand (also known as CD154). This antigen is an essential immune system trigger for B-cell activation

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and antibody production. Potential target indications include antibody-mediated autoimmune diseases such as ITP and T-cell-mediated diseases such as MS. The development of our humanized anti-CD40L monoclonal antibody, IDEC-131, is based on technology that we licensed from Dartmouth College, where researchers have shown that the binding of CD40L to its CD40 receptor on B cells is essential for proper immune system function. These researchers generated anti-CD40L antibodies that blocked this T-cell and B-cell interaction and halted disease progression in a variety of animal models of disease characterized by abnormal or unwanted immune response. Moreover, when researchers ended the animals' anti-CD40L treatments, the animals' antibody-producing capacity returned to normal levels, but their disease remained suppressed. Treatment with the anti-CD40L antibodies appeared to have reset the animals' immune systems and restored a normal immune response. Under the collaborative agreement, we have agreed to develop with Eisai a humanized anti-CD40L antibody. This effort has resulted in the identification of the humanized anti-CD40L antibody lead candidate, IDEC-131, which underwent preclinical testing, process development and manufacturing of clinical trial material in early 1997. We successfully completed a Phase I clinical trial in SLE with IDEC-131 in early 1999, which demonstrated an overall favorable safety profile. In the first quarter of 2000, we completed a Phase II clinical trial with IDEC-131 in patients with SLE that demonstrated a favorable safety profile. However, the response rates in this Phase II trial, versus a significant placebo effect, did not support continued development of IDEC-131 in SLE. In 2001, we initiated a Phase II study in patients with moderate to severe psoriasis. This latter trial was completed in 2002 and presentation of results is anticipated in 2003. We also commenced a Phase II trial in Crohn's disease in 2001. In June 2002, all clinical trials of IDEC-131 were placed on clinical hold

## IDEC-160

In September 2002, we entered into a license agreement with Shinyaku under which we in-licensed IDEC-160, an orally-active small-molecule. IDEC-160 is being initially developed by Shinyaku as a treatment for solid cancers, including colorectal, non-small cell lung and prostate cancer. Small molecule drugs are pharmaceutical compounds that enter cells and target specific biochemical events that result in disease or otherwise offer avenues to disease treatment. Because of their ability to reach cancerous cells deep within tumors, such drugs are often better suited than antibodies as treatments against solid tumors. Shinyaku has initiated two dose-escalating Phase I trials in the United States in patients with solid tumors. We plan to begin Phase II trials in the fourth quarter of 2003.

## IDEC-201

In January 2003, we entered into a collaboration agreement with Biogen under which we in-licensed three products, including IDEC-201. IDEC-201 is an interferon beta gene delivery system using a replication defective recombinant adenovirus vector. We will complete an ongoing Phase I/II study in patients with glial tumors that was begun by our licensor, Biogen. Biogen has future rights to participate in development and commercialization of IDEC-201.

## Strategic Alliances

We have entered into strategic partnering arrangements for many of our product development programs. Our entitlement to funding under the arrangements depends on achieving product

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development objectives related to development, clinical trial results, regulatory approvals and other factors. These arrangements include:

#### Genentech, Inc.

In March 1995, we entered into a collaborative agreement with Genentech for the clinical development and commercialization of our anti-CD20 monoclonal antibody, Rituxan, for the treatment of certain B-cell NHLs. Concurrent with the collaborative agreement, we also entered into an expression technology license agreement with Genentech for a proprietary gene expression technology developed by us and a preferred stock purchase agreement providing for various equity investments in us that have been made by Genentech.

We are copromoting Rituxan with Genentech in the United States. Our collaborative agreement with Genentech provides two independent mechanisms by which either party may purchase or sell its rights in the copromotion territory from or to the other party. Upon the occurrence of specified events that constitute a change of control in us, Genentech may elect to present an offer to us to purchase our copromotion rights. We must then accept Genentech's offer or purchase

Genentech's copromotion rights for an amount scaled (using the profit sharing ratio between the parties) to Genentech's offer. Under a second mechanism, after a specified period of commercial sales and upon a specified number of years of declining copromotion profits or if Genentech files for U.S. regulatory approval on a competitive product during a limited period of time, either party may offer to purchase the other party's copromotion rights. The offeree may either accept the offer price or purchase the offeror's copromotion rights at the offer price scaled to the offeror's share of copromotion profits. Under the terms of our Supply Agreement with Genentech, Genentech assumed worldwide manufacturing obligations for Rituxan beginning in September 1999.

Genentech has granted Roche exclusive marketing rights outside of the United States, except in Japan where Roche copromotes Rituxan in collaboration with Zenyaku. Outside the United States, Canada and Japan, Roche has elected to market rituximab under the trade name MabThera. We receive royalties from Genentech on sales of Rituxan outside the United States, except Canada, by Roche and Zenyaku. Royalties on sales of Rituxan in Canada are received directly from Roche.

Eisai Co., Ltd.

In December 1995, we entered into a collaborative development agreement and a license agreement with Eisai aimed at the development and commercialization of humanized and PRIMATIZED anti-CD40L antibodies. Under the terms of these agreements, we may receive milestone payments totaling up to \$12.5 million and research and development support payments totaling up to \$25.0 million, subject to the attainment of product development objectives and satisfaction of other criteria to be agreed upon between us and Eisai. We have recognized revenues totaling \$31.5 million under our agreements with Eisai through December 31, 2002. Eisai received exclusive rights in Asia and Europe to develop and market products resulting from the collaboration, with us receiving royalties on eventual product sales by Eisai. At any time, Eisai may terminate the development agreement by giving us 60 days' written notice based on a reasonable determination that the products do not justify continued development or marketing.

## Mitsubishi Pharma Corporation

In September 2001, we entered into an extension of our collaborative agreement with Mitsubishi, which originally expired in 1996, for the development of a PRIMATIZED anti-CD80 (anti-B7.1) antibody. Additionally, we have an ongoing license agreement with Mitsubishi that was entered into in November 1993. Under the terms of these agreements, we may receive milestone payments totaling up to \$22.0 million, subject to the attainment of product development objectives, as well as certain

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research and development support payments. We have recognized revenues totaling \$17.8 million under our agreements with Mitsubishi through December 31, 2002. Under the license agreement, we granted Mitsubishi an exclusive license in Asia to manufacture, use and sell PRIMATIZED anti-CD80 (anti-B7.1) antibody products. We will receive royalties on sales by Mitsubishi of any developed products. Mitsubishi may terminate the license at any time upon 30 days' written notice, only after completion of Phase II clinical trials or for certain protocol changes in planned clinical trials for IDEC-114.

## Seikagaku Corporation

In December 1994, we entered into a collaborative development agreement and a license agreement with Seikagaku aimed at the development and commercialization of therapeutic products based on our PRIMATIZED anti-CD23 antibodies. Under the terms of these agreements, we may receive milestone and research and development support payments totaling up to \$26.0 million, subject to the attainment of product development objectives, as well as reimbursement for certain other research and development expenses incurred under our PRIMATIZED anti-CD23 antibody development program. We have recognized revenues totaling \$18.1 million under these agreements through December 31, 2002. Under the license agreement, Seikagaku received exclusive rights worldwide, except North, Central and South America, to all products emerging from the collaboration. We will receive royalties on any eventual product sales by Seikagaku. At any time, Seikagaku may terminate the development agreement and the license agreement by giving us 30 days' written notice based on a reasonable determination that the products do not justify continued development or marketing.

### Schering Aktiengesellschaft

In June 1999, we entered into a collaboration and license agreement and a supply agreement with Schering AG aimed at the development and commercialization of our radioimmunotherapy Zevalin. Under the terms of these agreements, we may receive milestone and research and development support payments totaling up to \$47.5 million, subject to the attainment of product development objectives. We have recognized \$34.7 million under these agreements through December 31, 2002. Under these agreements, Schering AG received marketing and distribution rights to Zevalin outside the United States, and we will receive royalties on eventual product sales by Schering AG. Under the terms of a separate supply agreement, we are obligated to meet Schering AG's clinical and commercial requirements for Zevalin. Schering AG may terminate these agreements for any reason.

## Manufacturing

From our inception, we have focused on establishing and maintaining a leadership position in cell culture techniques for antibody manufacturing. Cell culture is a method for manufacturing of clinical and commercial grade protein products by reproducible techniques at various scales, up to many kilograms of antibody. Our manufacturing technology is based on the suspension culture of mammalian cells in stainless steel vessels. Suspension culture fermentation provides greater flexibility and more rapid production of the large amounts of antibodies required for product commercialization and pivotal trials. We believe that our current manufacturing facility is one of a limited number approved for any type of mammalian cell fermentation, for example, the process used in Rituxan. Our current manufacturing facility has been approved by the FDA for the commercial manufacture of certain components of Rituxan and Zevalin.

In September 1999, we transferred all worldwide manufacturing activities for bulk Rituxan to Genentech. Since the transfer of bulk Rituxan manufacturing to Genentech and prior to receiving FDA approval for Zevalin in February 2002, we have been using our available manufacturing capacity for production of specification-setting lots and commercial inventory of the Zevalin antibody and for

production of clinical material for our other products under development. We currently manufacture our own commercial requirements of the antibody for Zevalin. Zevalin has multiple components that require successful coordination among several third-party contract manufacturers and suppliers. We have no fill/finish experience or capacity and we do not have manufacturing experience or facilities for small molecule manufacturing, chelates or radioisotopes and, therefore, we are dependent on outside contractors and suppliers to meet these needs. In 2001, we entered into an agreement with DSM Pharmaceuticals to meet our commercial manufacturing demands for the fill/finish of Zevalin bulk product. In 2002, we entered in an agreement with Baxter Pharmaceutical Solutions LLC to perform fill/finish operations for commercial quantities of Zevalin. In 1999, we entered into an agreement, which we have subsequently amended, with MDS Canada for the development and supply of the radioisotope yttrium-90 used with our Zevalin product. Under the terms of the agreement, as amended, MDS Canada has agreed to supply, with certain exceptions, the yttrium-90 required to meet the clinical and commercial needs in the United Sates and Canada for Zevalin and selected other products under development. The initial term of the agreement expires five years following commercialization of Zevalin. We have agreed to guarantee MDS Canada a minimum purchase level of yttrium-90 over the duration of the initial term. In addition, MDS Canada has agreed to establish a new manufacturing facility to meet our yttrium-90 supply needs. Upon completion of this facility, MDS Canada can transition supply of yttrium-90 from its existing facilities to the new facility. To secure our minimum purchase commitments and in connection with MDS Canada's agreement to establish a new manufacturing facility, we have agreed to make periodic payments into an escrow account. As of December 31, 2002, we have paid \$22.5 million into this escrow fund. The agreement may be terminated by either party upon the bankruptcy of, or a material breach by, the other party. In addition, we can terminate the agreement following our satisfaction of the minimum purchase commitments, or earlier if we agree to forfeit a portion of the funds in the escrow account. Further, MDS Canada cannot terminate the agreement until five years following the date that its new manufacturing facility is established and capable of producing yttrium-90.

We are currently constructing a large-scale manufacturing facility on an 87-acre site in Oceanside, California that we anticipate using to commercialize our products currently in clinical trials if they are approved by the FDA. We believe that there is a limited manufacturing capacity in our market for production of biologics products. We expect the first phase of the new facility to be mechanically completed in 2004, followed by commissioning and validation in 2005 and 2006. This facility will allow us to better control the manufacture of our products, thus reducing our reliance on contract manufacturers, as well as to reduce commercial supply risk. We also have a facility, adjacent to our 87-acre site in Oceanside, to be used potentially for the manufacture of the Zevalin bulk antibody, drug supply for certain of our clinical trials and drug supply for any potential product launches prior to 2005. We are currently performing validation activities and we anticipate the facility will be equipped and in operation by mid-2003.

## Sales and Marketing Strategy

We currently depend on the successful marketing and sales of Rituxan for much of our anticipated revenue. Rituxan is marketed and sold in the United States under a copromotion agreement with Genentech. Genentech currently has a sales and marketing staff dedicated to Rituxan. To fulfill our duties under the copromotion agreement, we also have a marketing staff and a sales organization with experience primarily in oncology therapy and who, until we received approval from the FDA for Zevalin, were dedicated exclusively to the commercialization of Rituxan. We rely heavily on Genentech to supply marketing support services for Rituxan including customer service, order entry, shipping, billing, customer reimbursement assistance, managed care sales support, medical information and sales training.

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Zevalin is our first product to be solely marketed by us in the United States. We have expanded our sales and marketing staff to support the distribution of Zevalin in the United States. Our sales efforts are focused primarily on specialist physicians in private practice or at major medical centers in the United States with expertise in oncology, hematology and/or nuclear medicine. In general, we sell Zevalin to radiopharmacies that radiolabel, or combine, the Zevalin antibody with indium-111 and yttrium-90 and then distribute the finished product to hospitals or licensed treatment facilities for administration. We use common pharmaceutical company marketing techniques, including sales representatives calling on individual physicians, medical education programs, professional symposia, promotional materials and public relations.

We have limited marketing support service experience and, therefore, we will be dependent on outside contractors to meet those needs. We currently have a contract with a third-party logistics distributor to provide customer service, order entry, shipping, billing, customer reimbursement assistance and managed care sales support.

Outside North America, we have adopted a strategy to pursue collaborative arrangements with established pharmaceutical companies for marketing, distribution and sale of our products.

## **Patents and Proprietary Technology**

The biopharmaceutical field is characterized by a large number of patent filings. A substantial number of patents have already been issued to other biotechnology and biopharmaceutical companies. Particularly in the monoclonal antibody and recombinant deoxyribonucleic acid, or DNA, fields, competitors may have filed applications for, or have been issued patents and may obtain additional patents and proprietary rights relating to, products or processes competitive with or similar to our products or processes. Moreover, United States and foreign country patent laws are distinct and the interpretations thereunder unique to each country. Thus, patentability, validity and infringement issues for the same technology or inventions may be resolved differently in different jurisdictions. We cannot assure you that patents do not exist in the United States or in foreign countries or that patents will not be issued that would harm our ability to market our products. Accordingly, we expect that commercializing our products may require licensing and/or cross-licensing of patents with other companies or institutions in the field. We cannot assure you that the licenses, which might be required for our processes or products, will be available on commercially acceptable terms, if at all. The ability to license any of these patents and the likelihood of successfully contesting the scope, validity or enforceability of the patents are uncertain and the related costs may be significant. If we are required to acquire rights to valid and enforceable patents but cannot do so at a reasonable cost, our ability to manufacture or market our products will be harmed.

We are the assignee of several issued U.S. patents, numerous patent applications and corresponding foreign patents and patent applications. Other patents or applications owned by third parties have been exclusively licensed, as in the case of anti-CD40L core technology licensed from Dartmouth College, or non-exclusively licensed by us.

We have several issued U.S. patents and U.S. patent applications, and numerous corresponding foreign counterparts directed to anti-CD20 antibody technology, including Rituxan and Zevalin. We have been granted patents covering Rituxan by the European Patent Office. Genentech, our collaborative partner for Rituxan, has secured an exclusive license to three U.S. patents and counterpart U.S. and foreign patent applications assigned to Xoma Corporation that relate to chimeric antibodies against the CD20 antigen. Genentech has granted to us a non-exclusive sublicense to make, have made, use and sell Rituxan under these

We have also filed for worldwide patent protection on our PRIMATIZED antibody technology. We have received several U.S. patents claiming various aspects of the PRIMATIZED antibody technology. These patents generically cover our PRIMATIZED antibody technology as well as PRIMATIZED antibodies to specific antigen targets.

We are aware of several third-party patents and patent applications which, to the extent they issue as patents and are successfully asserted against us, may significantly impair our ability to make, use, offer to sell, sell and import our products.

We have filed numerous trademark and service mark applications in the United States, Canada and in certain international markets. PRIMATIZED, Rituxan, Zevalin and IDEC Pharmaceuticals are registered trademarks in the United States. We also have trademark applications pending for other marks.

We also rely upon unpatented trade secrets, and we cannot assure you that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect such rights. We require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisers to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of our employees, the agreement provides that all inventions conceived by such employees shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

## **Research and Development**

Research and development expenses were \$93.6 million in 2002, \$86.3 million in 2001 and \$68.9 million in 2000, of which approximately 97% in 2002, 89% in 2001 and 78% in 2000, was sponsored by us and the remainder of which was funded pursuant to product development collaboration arrangements.

## Regulation of Products by the FDA

The testing, manufacturing, labeling, advertising, promotion, export and marketing, among other things, of our two approved products and our proposed products are subject to extensive regulation by governmental authorities in the United States and other countries. In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. Our two approved products are regulated by the FDA as biologics and we believe our proposed products, with the exception of IDEC-160 which we believe will be regulated by the FDA as a drug, will also be regulated by FDA as biologics. Biologics require the submission of a Biologics License Application, or BLA, and approval by the FDA prior to being marketed in the United States. Drugs require the submission of a New Drug Application, or NDA. The regulatory approval process for a NDA is similar to the approval process for a BLA. Manufacturers of biologics and drugs may also be subject to state regulation. Failure to comply with FDA requirements, both before and after product approval, may subject us and/or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines, injunctions and/or criminal prosecution.

The steps required before a product may be approved for marketing in the United States generally include (i) preclinical laboratory tests and animal tests, (ii) the submission to the FDA of an IND for

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human clinical testing, which must become effective before human clinical trials may commence, (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the product, (iv) the submission to the FDA of a BLA or NDA, (v) FDA review of the BLA or NDA and (vi) satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is made to assess compliance with cGMP. The testing and approval process requires substantial time, effort and financial resources and there can be no assurance that any approval will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of the product, as well as animal studies to assess the potential safety and efficacy of the product. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may be commenced. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA before that time raises concerns or questions about the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials.

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of qualified principal investigators. Further, each clinical study must be reviewed and approved by an independent Institutional Review Board.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into human subjects, the drug is usually tested for safety (adverse effects), dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics. Phase II usually involves studies in a limited patient population to (i) evaluate preliminarily the efficacy of the drug for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage and (iii) identify possible adverse effects and safety risks. Phase III trials generally further evaluate clinical efficacy and test further for safety within an expanded patient population. There can be no assurance that Phase I, Phase II or Phase III testing will be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of the preclinical studies and clinical studies, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of a BLA or NDA requesting approval to market the product. Before approving a BLA or NDA, the FDA will inspect the facilities at which the product is manufactured, and will not approve the product unless cGMP compliance is satisfactory. The FDA may deny a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require postmarketing testing and surveillance to monitor the safety or efficacy of a product. Approval entails limitations on the indicated uses for which a product may be marketed. When approval is granted under the "accelerated approval" provisions of FDA's regulations, the BLA or NDA holder must conduct certain additional studies to verify the clinical benefit attributable to the product. Failure to conduct the required studies, or to comply with certain other conditions of accelerated approvals, may result, following a hearing, in FDA's withdrawing or modifying that part of the approval that was granted under the accelerated approval provisions. One of the indications for which Zevalin was approved was an accelerated approval, so if we fail to conduct the required studies or otherwise fail to comply with the conditions of accelerated approval, the FDA may take action to seek to withdraw that approval. Also, if we seek to make certain changes to an approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components, we will need FDA review and approval before the change can be implemented.

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BLA or NDA holders must continue to comply with FDA requirements after approval. For example, BLA or NDA holders are required to report certain adverse reactions to the FDA and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP regulations after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, monies and effort in the area of production and quality control to maintain cGMP compliance. In addition, discovery of problems, such as safety problems, may result in changes in labeling or restrictions on a product, manufacturer or BLA or NDA holder, including removal of the product from the market.

We will also be subject to a variety of regulations governing clinical trials and sales of our products outside the United States. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. At least initially, we intend, to the extent possible, to rely on foreign licensees to obtain regulatory approval for marketing our products in foreign countries.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in certain very limited circumstances.

Rituxan, Zevalin and IDEC-152 have received orphan drug exclusivity in the United States. There can be no assurance, however, that competitors will not receive approval of other different drugs or biologics for treatment of the diseases for which Rituxan and Zevalin are approved and IDEC-152 is targeted.

## **Our Executive Officers**

Information about our executive officers as of January 31, 2003 is set forth below:

Name	Age	Titles
William H. Rastetter, Ph.D.	54	Chairman, Chief Executive Officer
William R. Rohn	59	President and Chief Operating Officer
Paul C. Grint, M.D.	45	Senior Vice President and Chief Medical Officer
Nabil Hanna, Ph.D.	59	Senior Vice President and Chief Scientific Officer
Wolfgang Berthold, Ph.D.	55	Senior Vice President, Biopharmaceutical Sciences
John M. Dunn	51	Senior Vice President, Legal and Compliance, General Counsel and
		Corporate Secretary
Connie L. Matsui	49	Senior Vice President, Planning and Resource Development
Edward M. Rodriguez	42	Vice President, Finance and Controller
Michael E. Wiebe, Ph.D.	60	Vice President, Quality
Mark C. Wiggins	47	Vice President, Marketing and Business Development

Dr. Rastetter was appointed our Chairman of the Board of Directors on May 22, 1996. He was appointed as our Chief Executive Officer in December 1986 and served as President from 1986 to 2002

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and Chief Financial Officer from 1988 to 1993. Dr. Rastetter has served as one of our directors since 1986. From 1984 to 1986, he was Director of Corporate Ventures at Genentech. From 1982 to 1984, Dr. Rastetter served in a scientific capacity at Genentech, directing the Biocatalysis and Chemical Sciences groups. From 1975 to 1982, he held various faculty positions at the Massachusetts Institute of Technology. Dr. Rastetter is also a director of Argonaut Technologies, Inc. and Illumina, Inc. Dr. Rastetter received his S.B. in chemistry from the Massachusetts Institute of Technology and his M.A. and Ph.D. in chemistry from Harvard University.

Mr. Rohn joined us in August 1993 as Senior Vice President, Commercial and Corporate Development. Mr. Rohn was appointed Senior Vice President, Commercial Operations in April 1996. In May 1998, Mr. Rohn was promoted to Chief Operating Officer and in January 2002 was promoted to President and Chief Operating Officer. Prior to joining us, Mr. Rohn was employed by Adria Laboratories from 1984 until August 1993, most recently as Senior Vice President of Sales and Marketing with responsibilities for strategic and commercial partnerships as well as all sales and marketing functions in the United States. Prior to

Adria, Mr. Rohn held marketing and sales management positions at Abbott Laboratories, Warren-Teed Pharmaceuticals, Miles Laboratories and Mead Johnson Laboratories. Mr. Rohn is also a director of Pharmacyclics, Inc. and Cerus Corporation. Mr. Rohn received a B.A. in Marketing from Michigan State University.

Dr. Grint joined us as Chief Medical Officer and Senior Vice President, Medical and Clinical Research and Development in January 2001. Prior to joining us, Dr. Grint was employed with Schering-Plough Research Institute from 1992 to 2000 holding a number of positions of increasing responsibility, most recently as Vice President of Clinical Immunology and Biotechnology. In addition, he was chairman of the Biotechnology Therapy Team and an Honorary Lecturer in the Department of Virology at St. Bartholomew's Hospital in London. Dr. Grint received his medical degree at University of London, St. Bartholomew's Hospital Medical College, London and is a Fellow of the Royal College of Pathologists.

Dr. Hanna joined us in February 1990 as Vice President, Research and Preclinical Development. In August 1993, Dr. Hanna was promoted to Senior Vice President, Research and Preclinical Development and in May 1998 he was promoted to Chief Scientific Officer. From 1981 to 1990, Dr. Hanna served as Associate Director and then Director of the Department of Immunology at SmithKline Beecham focusing on autoimmune and chronic inflammatory diseases. From 1978 to 1981, he was a research scientist at the NCI-Frederick Cancer Research Center, where he studied the role of immune system cells in host defenses against cancer. From 1973 to 1978, Dr. Hanna was a lecturer in the Department of Immunology at the Hebrew University Medical School in Israel, where he received his Ph.D. in Immunology.

Dr. Berthold joined us in February 2000 as Senior Vice President, Biopharmaceutical Science. He previously served from 1995 to 2000 as Vice President Biopharmaceuticals at F. Hoffmann-La Roche Inc. and also served as International Advisor for all Roche pharmaceutical biotechnology projects in development. Previously, Dr. Berthold served as head of the Biotech Process Development Group for pharmaceutical biologics at Thomae/Boehringer Ingelheim from 1979 to 1995, which operates one of the world's largest biopharmaceutical manufacturing plants. Dr. Berthold received his Ph.D. in biochemistry from University of London, England.

Mr. Dunn joined us in January 2002 as Senior Vice President, Legal and Compliance, General Counsel and Secretary. Previously, Mr. Dunn had been a partner with Pillsbury Winthrop LLP and co-leader of the firm's Biotech, Pharmaceuticals and Healthcare Industry Team. He has been practicing law for 24 years, specializing in corporate and business representation of public and private companies. Mr. Dunn received his B.S. and J.D. from the University of Wyoming.

Ms. Matsui joined us in November 1992 as Senior Director, Planning and Resource Development with primary responsibility for strategic planning and human resources. Ms. Matsui was promoted to

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Vice President, Planning and Resource Development in December 1994 and to Senior Vice President, Planning and Resource Development in September 2000. Ms. Matsui's current responsibilities include investor relations, corporate communications, human resources, project management and strategic planning. From 1977 to 1991, she served in a variety of marketing and general management positions at Wells Fargo Bank including Vice President responsible for Consumer Retirement Programs and Vice President in charge of company wide Employee Relations and Communications. Ms. Matsui received her B.A. and M.B.A. from Stanford University.

Mr. Rodriguez joined us in December 1991 as Senior Manager of Finance and in April of 1996 he was promoted to Director of Finance. Mr. Rodriguez served as Senior Director of Finance from September 1999 to April 2001. In April 2001, he was appointed Vice President, Finance and Controller. Mr. Rodriguez received a B.S. from San Diego State University in business administration and earned his C.P.A. qualifications while working for KPMG LLP.

Dr. Wiebe joined us in July of 2001 as Vice President of Quality. From 1984 to 1998 he held various positions at Genentech, including Senior Director of Quality Control and from 1998 to 2001 he was Chief Scientific Officer for BioReliance Corporation. Dr. Wiebe received a B.S. from Sterling College in mathematics and received his Ph.D. in microbiology from the University of Kansas.

Mr. Wiggins joined us in May of 1998 as Vice President of Business Development. In November 2000, he was appointed to Vice President of Marketing and Business Development. From 1986 to 1996 he held various positions at Schering-Plough, including Director of Business Development and from 1996 to 1998 he was Vice President of Business Development and Marketing for Hybridon. Mr. Wiggins received a B.S. from Syracuse University in finance and received his M.B.A from the University of Arizona.

## **Our Employees**

As of January 31, 2003, we employed 995 persons. None of our employees is represented by a labor union or bound by a collective bargaining agreement. Our management believes that our overall relations with employees are good.

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# FORWARD-LOOKING INFORMATION AND RISK FACTORS THAT MAY AFFECT FUTURE RESULTS

This Form 10-K contains forward-looking statements based on our current expectations. These statements include, without limitation, statements about market opportunity, our growth and sale strategies and our expectations, plans and objectives. In some cases, you can identify these statements by terminology such as anticipate, believe, estimate, expect, intend, may, plan, should or will or similar phrases or expressions. You should be aware that these statements are projections or estimates as to future events, and actual results may differ materially.

In addition to the other information contained in this Form 10-K, you should consider the following risk factors which could affect our actual future results and could harm our business, financial condition and results of operations. The risks and uncertainties described below are not the only risks facing us and additional risks and uncertainties may also harm our business.

## Our Revenues Rely Significantly on Rituxan Sales.

Our revenues currently depend substantially upon continued sales of Rituxan. For the year ended December 31, 2002, approximately 95% of our revenues were derived from our Rituxan copromotion arrangement with Genentech. We cannot assure you that Rituxan will continue to be accepted in the United States or in any foreign markets or that Rituxan sales will continue to increase. A number of factors may affect the rate and level of market acceptance of Rituxan, including:

- the perception of physicians and other members of the health care community of its safety and efficacy or that of competing products, if any;
- the effectiveness of our and Genentech's sales and marketing efforts in the United States and the effectiveness of Roche's sales and marketing efforts outside the United States and Japan;
- unfavorable publicity concerning Rituxan or similar drugs;
- its price relative to other drugs or competing treatments;
- the availability and level of third-party reimbursement; and
- regulatory developments related to the manufacture or continued use of Rituxan.

Given our current reliance on Rituxan as the principal source of our revenue, any material adverse developments with respect to the commercialization of Rituxan may cause our revenue to decrease and may cause us to incur losses in the future.

# If We Fail to Commercialize Zevalin Successfully in the United States, to Obtain Marketing Approval for Zevalin in Europe or to Commercialize Zevalin Successfully in Europe, Our Business Could Be Harmed.

Our radioimmunotherapy product Zevalin was approved by the FDA for marketing and sale in the United States in February 2002 and we began selling the product in April 2002. We cannot assure you that Zevalin will be accepted or widely used by physicians and other members of the health care community in the United States. Further, marketing approval for Zevalin in Europe has been delayed pending approval by the EMEA of our manufacturing facilities and our fill/finish provider and we cannot be certain that, even if marketing approval is obtained, our exclusive worldwide marketing partner, Schering AG, will be able to commercialize Zevalin successfully in Europe. Factors that might impact the successful commercialization of Zevalin include:

the perception of physicians and other members of the healthcare community of its safety and efficacy or that of competing products, if any;

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- unfavorable publicity concerning Zevalin or similar drugs;
- its price relative to other drugs or competing treatments;
- the availability and level of third-party reimbursement;
- regulatory developments related to the manufacture or continued use of Zevalin;
- FDA approval and successful commercialization of Bexxar® (tositumomab, iodine I-131 tositumomab) or other competitive products; and
- an adverse outcome of our patent litigation.

In addition, we have limited marketing support service experience and, therefore, we are dependent on outside contractors to meet those needs for Zevalin. For example, we rely upon a third-party logistics distributor to provide customer service, order entry, shipping and billing. Customer reimbursement assistance is provided by a separate outside contractor. We cannot assure you that the integration of these marketing support services can be successfully coordinated. Further, given our limited marketing and sales experience, we cannot assure you that we will be successful in selling Zevalin in the United States.

We rely on MDS Canada to provide the yttrium-90 radioisotope required for therapeutic use of Zevalin, and we rely on third parties for various manufacturing steps of Zevalin. In addition, there are currently only two sources approved by the FDA to supply the indium-111 isotope required for the imaging use of Zevalin. If we were to lose the services of any of these parties, we would be forced to find other providers, which could delay our ability to sell Zevalin. In addition, each of these third-party providers is subject to continuing inspection by the FDA or comparable agencies in other jurisdictions. A delay or an interruption in the manufacture of Zevalin or the production or availability of the yttrium-90 radioisotope or the indium-111 isotope for any reason, including as a result of a failure to pass any regulatory agency inspection could significantly impair our ability to sell Zevalin.

## We May Be Unable to Develop and Commercialize New Products.

Our future results of operations depend to a large extent upon our ability to successfully develop and commercialize new products in a timely and competitive manner. As a result, we must continue to develop, test and manufacture new products and then must meet regulatory standards and obtain regulatory approvals for any new products. Our products currently in development may not receive the regulatory approvals from the FDA or comparable agencies in other jurisdictions necessary to market these products. Additionally, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, will be successfully commercialized or competitive in the marketplace. Our business could be harmed if we were to experience delays or unanticipated costs in any part of the development process, if we were unable to obtain the regulatory approvals required to market the products we may develop, if we are unable to effectively commercialize products we may develop, or if we cannot secure or maintain manufacturing facilities in compliance with all applicable regulatory requirements.

## $\label{lem:contract} \textbf{We Have Limited Manufacturing Experience and Rely Heavily on Contract Manufacturers.}$

We rely heavily upon third-party manufacturers to manufacture significant portions of Zevalin and our product candidates. Our current manufacturing capacity is limited. Our manufacturing experience to date has been limited to the production of preclinical and clinical quantities of product candidates, approximately three years of commercial production of bulk Rituxan and portions of our commercial requirements of the bulk antibody for Zevalin. We have no

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manufacture of most of our product components. We cannot assure you that either our manufacturing facilities or our ability to sustain ongoing production of our products will be able to meet our expectations. If our current third-party manufacturers or service providers fail to meet our expectations, we may not be able to enter into satisfactory agreements with other third party manufacturers or service providers.

Zevalin has multiple components that require successful coordination among ourselves and several third-party contract manufacturers and suppliers. We may not be able to integrate and coordinate successfully our contract manufacturers and suppliers. In addition, our contract manufacturers and suppliers are required to maintain compliance with current Good Manufacturing Practices, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm this compliance. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA and ultimate amendment acceptance by the FDA prior to release of product to the market place. Their inability to demonstrate ongoing cGMP compliance and produce Zevalin components could interrupt commercial supply of Zevalin. If Zevalin production was interrupted or our third-party manufacturer was unable to manufacture adequate commercial quantities of Zevalin in a timely manner, it could harm our business.

We rely on Genentech for all Rituxan manufacturing to meet worldwide requirements. We cannot assure you that Genentech will manufacture and fill/finish Rituxan in sufficient quantities and on a timely and cost-effective basis or that Genentech will obtain and maintain all required manufacturing approvals. Genentech's failure to manufacture and fill/finish Rituxan or obtain and maintain required manufacturing approvals could harm our business.

From our manufacturing facilities, we have manufactured and will continue to manufacture our own commercial requirements of the bulk antibody and other kit components for Zevalin. We cannot assure you that our manufacturing performance will meet our expectations. Our inability to maintain regulatory approval of our manufacturing facility for Zevalin would harm our ability to timely produce commercial supplies of the Zevalin antibody. To the extent we cannot produce our own biologics, we will need to rely on third-party manufacturers, of which there are only a limited number capable of manufacturing biologics products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers.

Poor performance or coordination on our part or that of our third-party manufacturers or service providers could harm our business.

## We Rely Heavily on a Limited Number of Suppliers.

Some materials used in Rituxan, Zevalin and our product candidates are currently available only from a single supplier or a limited number of suppliers. Some of these suppliers are subject to ongoing FDA approvals or other governmental regulations. Any interruption or delay in our supply of materials required to sell our products could harm our business if we were unable to obtain an alternative supplier for these materials in a cost-effective and timely manner. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. These factors may be completely out of our control.

For example, we have entered into an agreement with MDS Canada, the commercial supplier of the yttrium-90 radioisotope for Zevalin, and will rely upon MDS Canada to supply our clinical and commercial requirements. If MDS Canada does not maintain FDA approvals or approvals of comparable agencies in other jurisdictions to produce the radioisotope yttrium-90 for Zevalin, or if we are unable to receive an adequate supply of this radioisotope for any other reason, including those described above, we would be unable to sell Zevalin for therapeutic use unless we were to obtain a new supplier. We are aware of other entities that may be able to provide the radioisotope that we need for

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the therapeutic use of Zevalin but we believe that these suppliers would be required to apply for additional governmental approvals to do so. The process of establishing a relationship with another supplier and the process of obtaining the required governmental approvals would be time consuming and uncertain. We cannot assure you that we could reach an agreement with another supplier in a timely manner or on commercially reasonable terms, if at all. As a result of these concerns, if we were to lose our supply or were unable to receive sufficient quantities of the radioisotope from our sole supplier, our ability to sell Zevalin could be harmed which, in turn, could harm our business.

## We Have Limited Sales and Marketing Experience.

We have limited experience with commercial sales and marketing, based entirely upon our launch and subsequent sales of Rituxan. Zevalin is our first product to be marketed exclusively by us in the United States. Outside the United States, our strategy for future products is to pursue and to rely solely upon collaborations with established pharmaceutical companies for marketing, distribution and sale of our products. We currently have no plans to directly market either of our products outside the United States. Given that we rely on Genentech to copromote Rituxan with us in the United States and rely exclusively on third parties to market Rituxan and Zevalin outside the United States, we cannot be certain that our products will be marketed and distributed in accordance with our expectations or that our market research or sales forecasts will be accurate. We have no marketing support service experience and, therefore, we will be dependent on outside contractors to meet those needs. We rely upon a third-party logistics distributor to provide customer service, order entry, shipping and billing. Customer reimbursement assistance is provided by a separate outside contractor. We cannot assure you that the integration of these marketing support services can be successfully coordinated. Neither can we assure you that we will ever be able to develop our own marketing and sales capabilities to an extent that we would not need to rely on third-party efforts, or that we will be able to maintain satisfactory arrangements with the third parties on whom we rely.

## Our Operating Results Are Subject to Significant Fluctuations.

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Fluctuation may result from a variety of factors, including:

• our achievement of product development objectives and milestones;

- demand and pricing for Rituxan and Zevalin;
- timing and nature of contract manufacturing and contract research and development payments and receipts;
- hospital and pharmacy buying decisions;
- clinical trial enrollment and expenses;
- research and development and manufacturing expenses;
- percentage of time that our manufacturing facilities are utilized for commercial versus clinical manufacturing;
- expenses related to protecting our intellectual property;
- physician acceptance of our products;
- government or private healthcare reimbursement policies;
- our manufacturing performance and capacity and that of our partners;
- amount and timing of sales orders for Rituxan by Genentech for customers in the United States and by Roche for customers outside the United States and Japan;

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- amount and timing of our sales orders for Zevalin for customers in the United States and, if approved in Europe, by Schering AG for customers outside the United States;
- rate and success of product approvals;
- timing of regulatory approval, if any, of competitive products and the rate of market penetration of competing products;
- collaboration obligations and copromotion payments we make or receive;
- interest rate fluctuations;
- foreign currency exchange rates; and
- overall economic conditions.

Our operating results during any one quarter do not necessarily suggest the anticipated results of future quarters.

## We Are Subject to Uncertainties Regarding Healthcare Reimbursement and Reform.

Our ability to commercialize products successfully depends in part on the extent to which health care providers are reimbursed by governmental agencies, including the Center for Medicare and Medicaid Services, or CMS, private health insurers and other organizations, such as health maintenance organizations, for the cost of such products and related treatments. Our business could be harmed if health care payers or providers implement cost-containment measures, or if governmental agencies implement health care reform. For example, CMS has indicated it may issue a National Coverage Decision (NCD) for the Zevalin therapeutic regimen which, if issued, might limit the patients and situations for which the Medicare program would provide reimbursement for Zevalin.

In addition, we cannot assure you that current or any future level of Medicare reimbursement for our products will be viewed favorably by health care providers and that they will prescribe our products as a result. For example, effective January 1, 2003, many anticancer drugs and biologics covered by the Medicare program, including Rituxan, were assigned new payment rates for use in the hospital outpatient setting. Although most patients do not receive Rituxan in the hospital outpatient setting and so the majority of patients will not be affected, this anomaly could cause some hospitals to decide not to provide Rituxan under certain circumstances. Also in January 2003, CMS classified the Zevalin therapeutic regimen as a procedure under HOPPS, rather than a drug, causing the baseline reimbursement rate set by CMS for Zevalin to be subject to adjustment based on a geographic wage index. CMS applies this index to procedure payments under its Hospital Outpatient Prospective Payment System, or HOPPS, to account for the regional variances in wages of hospital staff who perform health care services. As a result, in some lower-wage regions of the United States the level of reimbursement for Zevalin is less than the baseline rate and, concomitantly, less than the cost of acquiring the therapy. This anomaly could cause certain health care providers to decline to deliver the therapy in certain circumstances. Further, when the Zevalin therapeutic regimen is administered in a private-practice setting, such as a free-standing imaging center, payment rates for the Zevalin imaging and therapy doses are set by the local Medicare carrier and so may differ from carrier to carrier. As a result, if a health care provider in this setting deems a reimbursement rate to be insufficient, it could influence his or her decision whether to use Zevalin versus an alternative anticancer drug.

#### We Face Uncertain Results of Clinical Trials for Our Potential Products.

Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential products. The completion rate of clinical trials depends significantly upon the rate of patient enrollment. Our inability to enroll patients on a timely basis could result in increased expenses and product development delays, which could harm our business. We cannot assure

you that patients enrolled in our clinical trials will respond to our product candidates, that any product candidate will be safe and effective or that data derived from the trials will be suitable for submission to the FDA or satisfactorily support a BLA, sBLA or NDA. Factors that affect patient enrollment include:

- size of patient population for the targeted disease;
- eligibility criteria;
- proximity of eligible patients to clinical sites;
- · clinical trial protocols; and
- the existence of competing protocols, including competitive financial incentives for patients and clinicians, and existing approved drugs, including Rituxan in the case of Zevalin.

Even if a trial is fully enrolled, significant uncertainties remain as to whether it will prove successful. For example, in September 2002 we announced that we will not pursue further development of IDEC-114 for patients with moderate-to-severe psoriasis. In addition, we announced during the second quarter of 2002 that all ongoing clinical trials for our anti-CD40 ligand monoclonal antibody, IDEC-131, were put on clinical hold. We cannot predict when, if ever, we will resume clinical trials on IDEC-131.

In addition, the length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly and may be difficult to predict. Failure to comply with extensive FDA regulations may result in delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. The FDA may also suspend our clinical trials at any time if it concludes that the participants are being exposed to unacceptable risks. Consequently, we cannot ensure that Phase I, Phase II, Phase III or Phase IV post-marketing testing will be completed timely or successfully, if at all, for any of our potential or existing products. Furthermore, success in preclinical and early clinical trials does not ensure that later phase or large-scale trials will be successful.

## **Our Industry Is Intensely Competitive.**

The biotechnology industry is intensely competitive and we may not be able to produce or acquire rights to new products with commercial potential. We compete with biotechnology and pharmaceutical companies that have been established longer than we have, have a greater number of products on the market, have greater financial and other resources and have other technological or competitive advantages. We also compete in the development of technologies and processes and in acquiring personnel and technology from academic institutions, government agencies, and other private and public research organizations. We cannot be certain that one or more of our competitors will not receive patent protection that dominates, blocks or adversely affects our product development or business; will benefit from significantly greater sales and marketing capabilities; or will not develop products that are accepted more widely than ours.

One of our competitors, Corixa Corporation, formerly Coulter Pharmaceuticals, or Corixa, along with its marketing partner GlaxoSmithKline, plc, or Glaxo, is pursuing FDA approval for Bexxar, an investigational radioimmunotherapy for the treatment of low-grade or transformed low-grade NHL. We are aware that Corixa filed a revised BLA in 2001 and received a positive review by the FDA's Oncologic Drugs Advisory Committee, or ODAC, in December 2002. Although the FDA is not bound by ODAC's review, it often takes ODAC's recommendations into consideration when determining marketing approval of a new product. The new Prescription Drug User Fee Act goal date for the FDA to complete its review of all materials regarding Bexxar therapy is May 2, 2003. If Corixa successfully obtains FDA approval for Bexxar, our business could be harmed.

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We are also aware of other potentially competitive biologic therapies for non-Hodgkin's lymphoma in development.

# We May Be Unable to Adequately Protect or Enforce Our Intellectual Property Rights or Secure Rights to Third-Party Patents and We Are Involved in Patent Litigation.

Our ability and the abilities of our partners to obtain and maintain patent and other protection for our products will affect our ability to compete. We are assigned, have rights to, or have exclusive licenses to a number of U.S. and foreign patents and patent applications. However, the pending patent applications may not issue as patents and, even if approved, our patent rights may not be upheld by a court or may be narrowed if challenged. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Our patent rights may not provide competitive advantages for our products and may be challenged, infringed upon or circumvented by our competitors.

In addition to patents, we rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our partners, employees and consultants. These parties may breach our agreements and courts may not enforce the agreements, leaving us without adequate remedies. Further, our trade secrets may become known or be developed independently or patented by our competitors.

If it were ultimately determined that our claimed intellectual property rights are unenforceable, or that our use of our products infringes the rights of others, we may be required or may desire to obtain licenses to patents and other intellectual property held by third parties to develop, manufacture and market our products. We may not be able to obtain these licenses on commercially reasonable terms, if at all, and any licensed patents or intellectual property that we may obtain may not be valid or enforceable. In addition, the scope of intellectual property protection is subject to scrutiny and challenge by courts and other governmental bodies. Litigation and other proceedings concerning patents and proprietary technologies can be protracted, expensive and distracting to management and companies may sue competitors as a way of delaying the introduction of competitors' products. Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents in foreign countries or litigation against our partners, may be costly and time consuming and could harm our business.

Given the large number of patent filings in the biopharmaceutical field, our competitors may have filed applications or been issued patents and may obtain additional patents and proprietary rights relating to products or processes competitive with or similar to our products and processes. We cannot be certain that U.S. or foreign patents do not exist or will not issue that would harm our ability to commercialize our products and product candidates.

#### Patent Litigation Related to Rituxan

On May 28, 1999 and September 14, 2000, Glaxo filed two patent infringement lawsuits against Genentech. These suits asserted that the manufacture, use, and sale of Rituxan infringes U.S. patents owned by Glaxo. In September 2002, Genentech and Glaxo agreed to a settlement of both of these lawsuits, under which Genentech and Glaxo dismissed with prejudice all claims made by each party in the lawsuits and dismissed with prejudice Glaxo's appeal. The settlement resolves and ends all the patent infringement claims that Glaxo made against Genentech in these lawsuits.

Glaxo has also sued Roche in Germany asserting that Rituxan infringes Glaxo's patents. On October 26, 2000, a German court handling the infringement phase of the suit issued a decision holding that the manufacture, use and sale of Rituxan infringes patents held by Glaxo. Roche has appealed the decision and the appeal is pending before the Court of Appeals. At the end of 2001, a German court handling the validity phase of the trial held that the three patents were invalid. Additionally, Roche has filed oppositions in the European Patent Office, or EPO, to several of the Glaxo patents. Although we were not named in the suit, if Glaxo obtains an injunction precluding further sale of Rituxan in Europe, our business could be harmed.

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## Patent Litigation Related to Zevalin

On September 10, 2001, we filed a a lawsuit in the federal district court of Southern California against Corixa and the Regents of the University of Michigan seeking declaratory judgment that Zevalin and its use in the treatment of various B-cell NHLs does not infringe certain issued U.S. patents held by Corixa regarding products and processes relating to radioimmunotherapy and a further declaration that the patents are invalid. On September 12, 2001, Corixa, Glaxo (Corixa's marketing partner) and the University of Michigan filed a lawsuit against us in federal court in the district of Delaware against us for patent infringement. The lawsuit claims that we infringe the patents that are the subject of our declaratory judgment action against Corixa. The lawsuit against us seeks damages and to permanently enjoin us from selling Zevalin. This action has been transferred to the federal court for the Southern District of California and has been consolidated with our lawsuit. We cannot predict or determine the outcome of this litigation. An unfavorable outcome in this matter could limit our ability to sell Zevalin, could require us to pay damages for past sales of Zevalin and could require that we obtain a license from third parties to sell Zevalin. Any such unfavorable outcome could harm our business and our results of operations.

On September 10, 2001, we filed a second lawsuit in the federal district court in the Southern District of California against Glaxo seeking declaratory judgment that our manufacture of Zevalin does not infringe certain issued U.S. patents of Glaxo relating to cell culture media and further that Glaxo's patents are invalid. In November 2002, we settled the lawsuit and received a non-exclusive license under the Glaxo patents in exchange for payment of a lump-sum license fee.

On February 25, 2003, we filed an additional complaint against Corixa and Glaxo in the federal district court in the Southern District of California. The complaint alleges that Corixa's and Glaxo's conduct since ODAC's recommendation for approval of Bexxar constitutes, or will constitute, infringement of a patent recently issued to us. The complaint seeks available remedies under patent laws, including monetary damages and permanent injunctive relief.

## Proceedings Related to Anti-CD40L Antibodies

In September 1999, an interference to determine priority of inventorship was declared in the United States Patent and Trademark Office, or USPTO, between Dartmouth University's patent application, which has been exclusively licensed to us, and Columbia University's patent, which we believe has been exclusively licensed to Biogen, Inc., relating to anti-CD40L antibodies. In October 2001, the USPTO issued a decision concluding that there was no interference between the Dartmouth application and the Columbia patent. We appealed the decision to the Court of Appeals, Federal Circuit in December 2001. If the decision of the USPTO is upheld, the Columbia patent will remain in force and could be asserted against us.

We, along with other companies, have filed oppositions to a Japanese patent assigned to Immunex Corporation relating to anti-CD40L antibodies. We are also aware that oppositions have been filed in the EPO to granted European applications that have been licensed to us. Each of these applications contain claims relating to the use of anti-CD40L antibodies as a therapeutic. If the outcome of any of the oppositions is adverse, in whole or in part, it could result in the scope of some or all of the granted claims being limited, some or all of the granted claims being lost, the granted patent application not proceeding to a patent or our competitors having patent claims that may be asserted against us.

## Potential Conflicts with Third-Party Patent Rights

We are aware of several third-party patents and patent applications, to the extent they issue as patents, that if successfully asserted against us may adversely affect our ability to make, use, offer to sell, sell and import our products. These third-party patents and patent applications may include a

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number of U.S. and foreign patents that relate to various aspects of our products and product candidates.

The owners, or licensees of the owners of these patents, or any foreign patents, and patent applications, to the extent they issue as patents, may assert that one or more of our products infringe one or more claims of these patents. If legal action is commenced against us or our partners to enforce any of these patents and patent applications, to the extent they issue as patents, and the plaintiff in such action prevails, we could be prevented from practicing the subject matter claimed in these patents.

## Failure to Obtain Product Approvals or Comply with Government Regulations Could Harm Our Business.

As pharmaceutical companies, we and our partners, contract manufacturers and suppliers are subject to rigorous and extensive regulation by governmental authorities in the United States and other countries. In the United States, our products cannot be marketed until they are approved by the FDA. Obtaining FDA approval involves the submission, among other information, of the results of preclinical and clinical studies on the product and requires substantial time, effort and financial resources. The FDA will also conduct prelicensing and regular post-licensing inspections of the facility or facilities at which the product is manufactured to determine compliance with cGMP. Rituxan and Zevalin are our only products that have received FDA approval, and we cannot assure you that any of our product candidates will be approved either in the United States or in other countries in a timely fashion, or at all. Failure to comply with FDA

requirements, both before and after product approval, may subject us or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines, injunctions or criminal prosecution.

#### We May Be Unable to Maintain Third-Party Research and Development Relationships.

Funding of research and development efforts depends largely upon various arrangements with corporate partners and others who provide us with funding and who perform research and development with respect to our products. These corporate partners generally may terminate their arrangements with us at any time. These parties may develop products that compete with ours, and we cannot be certain that they will perform their contractual obligations or that any revenues will be derived from such arrangements. The failure of one or more of our corporate partners to achieve product development objectives could harm our ability to fund related programs and develop products.

#### Our Business Exposes Us to Product Liability Claims.

Our design, testing, development, manufacture and marketing of products involve an inherent risk of exposure to product liability claims and related adverse publicity. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. Although we currently maintain product liability insurance for our products in the amounts we believe to be commercially reasonable, we cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost or if a successful product liability claim is made against us, whether fully covered by insurance or not, our business could be harmed.

## We May Not Be Able to Successfully Develop and Commence Operations of Our New Manufacturing and Clinical Facilities.

We own an 87-acre parcel of land and a building on adjacent property in Oceanside, California where we are developing commercialand clinical manufacturing facilities. We have limited experience in developing commercial facilities and may not be able to successfully develop or commence operations

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at these facilities. If we fail to successfully develop or commence operations at these new facilities, we may be unable to commercialize or meet demands for products we may develop in the future. We may encounter difficulties in designing, constructing and initiating these facilities, including:

- governmental regulation of our facilities, specifically, FDA or comparable agency approvals required for the commercial manufacture of our products;
- public opinion regarding the impact of the facilities on nearby communities;
- construction delays, including obtaining necessary governmental approvals and permits;
- cost overruns;
- delays in design, shipment and installation of equipment for our facilities;
- natural disasters;
- · other unforeseeable factors inherent in the construction process; and
- obtaining financing we may need to complete the facilities.

Even if we are able to successfully develop these facilities, we may not be able to do so in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs or our future manufacturing needs may not be sufficient to allow the facility to be fully operational, any of which could harm our business.

## Our Business Involves Environmental Risks.

Our business and the business of several of our strategic partners, including Genentech, involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Biologics manufacturing is extremely susceptible to product loss due to microbial or viral contamination, material equipment failure, or vendor or operator error. Although we believe that our safety procedures for handling and disposing of such materials complies with state and federal standards, there will always be the risk of accidental contamination or injury. In addition, microbial or viral contamination may cause the closure of a manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. We currently store our radioactive materials on-site because the approval of a disposal site in California for all California-based companies has been delayed indefinitely. If and when a disposal site is approved, we may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could harm our business.

## We Rely Upon Key Personnel.

Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers and key scientific personnel. If we lose the services of any of these individuals, our business could be harmed. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales and manufacturing personnel and our ability to develop and maintain relationships with qualified clinical researchers. Competition to obtain the services of these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel or develop and maintain relationships with clinical researchers.

#### Future Transactions May Harm Our Business or the Market Price of Our Securities.

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

- mergers;
- acquisitions;
- strategic alliances;
- licensing agreements; and
- copromotion agreements.

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations to the market price of securities that we have issued. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also harm the market price of securities that we have issued.

## Volatility of Our Stock Price.

The market prices for our common stock and for securities of other companies engaged primarily in biotechnology and pharmaceutical development, manufacture and distribution are highly volatile. For example, the market price of our common stock fluctuated between \$20.76 per share and \$71.40 per share during the year ended December 31, 2002. The market price of our common stock likely will continue to fluctuate due to a variety of factors, including:

- material public announcements;
- the announcement and timing of new product introductions by us or others;
- technical innovations or product development by us or our competitors;
- regulatory approvals or regulatory issues;
- availability and level of third-party reimbursement;
- developments relating to patents, proprietary rights and orphan drug status;
- actual or potential clinical results with respect to our products under development or those of our competitors;
- political developments or proposed legislation in the pharmaceutical or healthcare industry;
- economic and other external factors, disaster or crisis;
- hedge and/or arbitrage activities by holders of our convertible promissory notes;
- period-to-period fluctuations in our financial results or results which do not meet or exceed analyst expectations; and
- market trends relating to or affecting stock prices throughout our industry, whether or not related to results or news regarding us or our competitors.

## We May Be Unable to Raise Additional Capital.

We expend and will likely continue to expend substantial funds to complete the research, development, manufacturing and marketing of our potential future products. Consequently, we may seek to raise capital through collaborative arrangements, strategic alliances or equity and debt financings or from other sources. We may need to raise additional funds or borrow funds to complete

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the construction of our planned facilities. We may be unable to raise additional capital on commercially acceptable terms, or at all, and if we raise capital through equity financing, existing stockholders will have their ownership interests diluted. Our failure to generate adequate funds from operations or from additional sources to fund our business objectives would harm our business.

#### Our Outstanding LYONs Leverage Us Considerably.

As a result of issuing our LYONs due 2019 in February 1999 and issuing our LYONs due 2032 in April and May 2002, we incurred indebtedness of approximately \$345.0 million at maturity in 2019 and approximately \$1.2 billion at maturity in 2032. As a result of this indebtedness, our principal and interest obligations increased substantially. In addition, holders of the senior notes may require us to purchase all or a portion of the senior notes on April 29, 2005, 2007, 2012 and 2017 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable at our option in cash, our common stock or a combination thereof. The degree to which we are leveraged could harm our ability to obtain future financing and could make us more vulnerable to industry

downturns and competitive pressures. Our ability to meet our debt obligations will be dependent upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

#### We Have Adopted Several Anti-takeover Measures.

A number of factors pertaining to our corporate governance discourage a takeover attempt that might be beneficial to stockholders who wish to receive a premium for their shares from a potential bidder. For example:

- we are subject to Section 203 of the Delaware General Corporation Law which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in the code section;
- our stockholder rights plan is designed to cause substantial dilution to a person who attempts to acquire us on terms not approved by our board of directors;
- our board of directors has the authority to issue, without vote or action of stockholders, up to 8,000,000 shares of preferred stock and to fix the price, rights, preferences and privileges of those shares. Any series of preferred stock could contain dividend rights, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences or other rights superior to the rights of holders of common stock. Although we currently have 36,214 shares of non-voting convertible preferred stock outstanding, which were convertible into 2,172,840 shares of common stock as of December 31, 2002, our board of directors has no present intention of issuing any additional shares of preferred stock. However, our board of directors may issue additional series of preferred stock in the future;
- our copromotion arrangement with Genentech provides Genentech with the option to buy the rights to Rituxan in the event that we undergo a change of control or we introduce a competing product, which may limit our attractiveness to potential acquirors;
- under the terms of the LYONs any acquiror would be required to repurchase the LYONs for cash in connection with its acquisition of us before 2007; and
- · our directors are elected to staggered terms, which prevents the entire board from being replaced in any single year.

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#### Item 2. Properties.

We currently lease approximately 315,000 square feet of administrative, research and development, manufacturing and warehouse space at four locations in San Diego, California. Our primary manufacturing plant is located at 11011 Torreyana Road in San Diego, California. This facility is leased under a 15-year operating lease that commenced in 1993. We have the option to extend the term of this lease for two consecutive periods of five years each. We lease additional administrative, executive office and warehouse space at 3030 Callan Road in San Diego, California. This facility is leased under a 13 year and 8 month operating lease that commenced in 1996. We have the option to extend the term of this lease for two consecutive periods of five years each. In June 1999, we entered into a 10-year operating lease for a research and development facility at 3010 Science Park Road in San Diego, California. We have the option to extend the term of this lease for two consecutive periods of five years each. In February 2002, we entered into a 4-year operating lease for additional administrative space at 10996 Torreyana Road in San Diego, California.

We own a building in Oceanside, California and we are currently performing validation activities in this facility. This facility will be used potentially for the manufacture of Zevalin bulk antibody, drug supply for certain of our clinical trials and drug supply for any potential product launches prior to 2005. We also own approximately 42.6 acres of land in San Diego, California and 87 acres of land in Oceanside, California. We are currently constructing a corporate headquarters and research and development campus on the San Diego land that is expected to be completed in mid 2004. We are currently building a large-scale manufacturing facility on the Oceanside land. We expect the first phase of this facility to be mechanically completed in 2004, followed by commissioning and validation in 2005 and 2006, respectively.

## Item 3. Legal Proceedings.

On May 28, 1999 and September 14, 2000, Glaxo filed two patent infringement lawsuits against Genentech. These suits asserted that the manufacture, use, and sale of Rituxan infringes U.S. patents owned by Glaxo. In September 2002, Genentech and Glaxo agreed to a settlement of both of these lawsuits, under which Genentech and Glaxo dismissed with prejudice all claims made by each party in the lawsuits and dismissed with prejudice Glaxo's appeal. The settlement resolves and ends all the patent infringement claims that Glaxo made against Genentech in these lawsuits.

In addition, Glaxo sued Roche in Germany and has asserted that Rituxan infringes Glaxo's patents. On October 26, 2000, a German court issued a decision holding that the manufacture, use and sale of Rituxan infringes patents held by Glaxo. Roche has appealed the decision and the appeal is pending before the Court of Appeal. If Glaxo elects to enforce the decision, it must post a \$6.4 million bond. At the end of 2001, a German court handling the validity phase of the trial held that the three patents were invalid. Although we were not named in the suit, if Glaxo obtains an injunction precluding further sale of Rituxan, or if it requires Roche to pay licensing fees for the further sale of Rituxan in Europe by Roche, our business could be harmed.

On September 10, 2001, we filed a lawsuit in the federal district court in the Southern District of California against Corixa and the University of Michigan seeking declaratory judgment that Zevalin and its use in the treatment of various B-cell NHLs does not infringe certain issued U.S. patents of Corixa regarding products and processes relating to radioimmunotherapy and a further declaration that Corixa's patents are invalid. On September 12, 2001, Corixa, Glaxo (Corixa's marketing partner) and the University of Michigan filed a lawsuit in the federal district court in the District of Delaware against us for patent infringement. The lawsuit claims that we infringe the patents that are the subject of our declaratory judgment action against Corixa. The lawsuit seeks damages and to permanently enjoin us from commercializing Zevalin. This action has been transferred to San Diego and will be consolidated with our lawsuit.

On September 10, 2001, we filed a second lawsuit in the federal district court in the Southern District of California against Glaxo seeking declaratory judgment that our manufacture of Zevalin does not infringe certain issued U.S. patents of Glaxo relating to cell culture media and further that Glaxo's patents are invalid. In November 2002, we settled the lawsuit and received a non-exclusive license under the Glaxo patents in exchange for payment of a lump-sum license fee.

On February 25, 2003, we filed an additional complaint against Corixa and Glaxo in the federal district court in the Southern District of California. The complaint alleges that Corixa's and Glaxo's conduct since ODAC's recommendation for approval of Bexxar constitutes, or will constitute, patent infringement. The complaint seeks available remedies under patent laws, including monetary damages and permanent injunctive relief.

In addition, we are involved in certain other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our business or financial condition.

## Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted to a vote of our stockholders during the last quarter of the year ended December 31, 2002.

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#### PART II

## Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans", is included under Item 12 of Part III of this Annual Report on Form 10-K.

#### (a) Market Information

Our common stock trades on The Nasdaq Stock Market under the symbol "IDPH." The following table shows the high and low sales price for our common stock as reported by The Nasdaq Stock Market for the years ended December 31, 2002 and 2001.

	Common Stock Frice							
		2002			2001			
		High		Low	High		Low	
First Quarter	\$	71.40	\$	50.09	\$	67.56	\$	32.63
Second Quarter		66.84		30.75		75.00		33.50
Third Quarter		47.67		20.76		69.60		44.78
Fourth Quarter		47.41		31.17		73.32		47.07

## (b) Holders

As of January 31, 2002 there were approximately 384 stockholders of record of our common stock.

## (c) Dividends

We have not paid cash dividends since our inception. We currently intend to retain all earnings, if any, for use in the expansion of our business and therefore do not anticipate paying any cash dividends in the foreseeable future.

(d) Recent sales of unregistered securities.

None

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## Item 6. Selected Consolidated Financial Data.

The following selected consolidated financial data should be read in conjunction with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, and the consolidated financial statements and related notes appearing elsewhere in this Form 10-K. Amounts are in thousands, except per share amounts.

### CONSOLIDATED STATEMENTS OF INCOME DATA:

	Y	ears ended December	31,	
2002	2001	2000	1999	1998

Common Stock Price

	_		_		_		_		_	
Revenues:										
Product sales	\$	13,711	\$	_	\$	_	\$	_	\$	_
Revenues from unconsolidated joint business arrangement		385,809		251,428		132,782		93,197		53,813
Corporate partner revenues	_	4,702		21,249		21,900		24,806		33,146
Total revenues		404,222		272,677		154,682		118,003		86,959
Operating costs and expenses:										
Cost of sales		1,457		_		_		_		_
Manufacturing costs		_		_		2,134		14,277		19,602
Research and development		93,648		86,299		68,922		42,831		31,485
Selling, general and administrative		95,241		55,241		27,767		19,478		16,968
Total operating costs and expenses		190,346		141,540		98,823		76,586		68,055
Income from operations		213,876		131,137		55,859		41,417		18,904
Interest income, net		17,646		30,467		13,488		4,189		2,996
Income before income tax provision and cumulative effect of accounting change Income tax provision		231,522 83,432		161,604 59,945		69,347 11,939		45,606 2,449		21,900 422
Income before cumulative effect of accounting change Cumulative effect of accounting change, net of income tax benefit of \$481		148,090		101,659		57,408 (9,263)		43,157		21,478 —
Net income	\$	148,090	\$	101,659	\$	48,145	\$	43,157	\$	21,478
Basic earnings per share(1):										
Before cumulative effect of accounting change	\$	0.97	\$	0.67	\$	0.43	\$	0.35	\$	0.18
Cumulative effect of accounting change		_		_		(0.07)		_		_
Basic earnings per share	\$	0.97	\$	0.67	\$	0.36	\$	0.35	\$	0.18
Diluted earnings per share(1):										
Before cumulative effect of accounting change	\$	0.85	\$	0.59	\$	0.36	\$	0.29	\$	0.15
Cumulative effect of accounting change						(0.06)				_
Diluted earnings per share	\$	0.85	\$	0.59	\$	0.30	\$	0.29	\$	0.15
Shares used in calculation of earnings per share(1):										
Basic		153,086		150,756		134,880		124,146		119,028
Diluted		179,634		181,481		159,310		151,287		140,262

<sup>(1)</sup> Earnings per share and share amounts for the years ended December 31, 2000, 1999 and 1998 have been restated to reflect our three-for-one stock split effected by way of a stock dividend in January 2001.

## **CONSOLIDATED BALANCE SHEETS DATA:**

_	December 31,								
	2002		2001		2000		1999		1998
Cash, cash equivalents and securities available-for-sale \$	1,447,865	\$	866,607	\$	750,526	\$	246,826	\$	73,502
Due from related parties	100,288		67,651		41,753		23,654		17,473
Total assets	2,059,689		1,141,216		856,406		307,074		125,273
Notes payable, less current portion	866,205		135,977		128,888		122,910		2,095
Retained earnings (accumulated deficit)	263,176		115,086		13,427		(34,718)		(77,875)
Total stockholders' equity	1,109,690		956,479		694,619		159,978		106,428

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Form 10-K.

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## Overview

We are primarily engaged in the research, development, manufacture and commercialization of targeted therapies for the treatment of cancer and autoimmune and inflammatory diseases.

In February 2002, Zevalin became the first radioimmunotherapy approved by the FDA for the treatment of certain B-cell NHLs. We have retained all United States marketing and distribution rights to Zevalin and have granted marketing and distribution rights outside the United States to Schering AG. In January 2001, the EMEA accepted for filing the Zevalin MAA, submitted by Schering AG in the European Union. In March 2002, the "Summary of Product Characteristics" was approved by the European CPMP for the treatment of adult patients with Rituximab relapsed or refractory CD20+ follicular B-cell NHL. In July 2002, we announced that marketing approval in Europe and European launch of Zevalin would be delayed. The CPMP's final approval is pending approval of our manufacturing facilities and fill/finish provider by the EMEA.

Our other product, Rituxan, is being copromoted in the United States under a joint business arrangement with Genentech, where we receive a share of the pretax copromotion profits. Under the copromotion arrangement, we share responsibility with Genentech for selling and continued development of Rituxan in the United States. Continued development of Rituxan includes conducting supportive research on Rituxan, post-approval clinical studies and obtaining approval of Rituxan for potential additional indications. Genentech provides the support functions for the commercialization of Rituxan in the United States including marketing, customer service, order entry, distribution, shipping and billing. Since September 1999, Genentech has been responsible for all worldwide manufacturing of Rituxan. Under the terms of separate agreements with Genentech, commercialization of Rituxan outside the United States is the responsibility of Roche, except in Japan where it copromotes Rituxan in collaboration with Zenyaku. We receive royalties on Rituxan sales outside the United States.

Our revenues include revenues from product sales of Zevalin, revenues from unconsolidated joint business arrangement and corporate partner revenues. Since the commercialization of Rituxan in November 1997, our revenues have depended primarily upon the sale of Rituxan.

We have incurred increasing annual operating expenses and, with the commercialization of Rituxan and Zevalin, we expect these trends to continue. Since our inception in 1985, through 1997, we incurred annual operating losses. Our ongoing profitability will be dependent upon the continued commercial success of Rituxan, the commercial success of Zevalin, product development and revenues from the achievement of product development objectives and licensing transactions. As of December 31, 2002, we had retained earnings of \$263.2 million.

#### **Critical Accounting Principles and Estimates**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires our management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On a periodic basis, we evaluate our estimates, including those related to revenue recognition and related allowances, inventory allowances, income taxes including the valuation allowance for deferred tax assets, valuation of long-lived assets and investments, and contingencies and litigation. These estimates are based on the information that is currently available and on various other assumptions that are believed to be reasonable. Actual results could vary from those estimates under different assumptions or conditions.

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Critical accounting policies and estimates are defined as those that are both most important to the portrayal of our financial condition and results of operations and require management's most subjective judgments. We have identified the following as the most critical accounting policies and estimates used in the preparation of our consolidated financial statements. See Note 1 to our consolidated financial statements for a description of our accounting policies.

Revenue recognition and related allowances: Revenues from sales of Zevalin are recognized upon shipment and transfer of title and risk of loss to the customer. We record allowances for estimated uncollectible accounts receivable, product returns and Medicaid rebates at the time of sale. Our estimates for uncollectible accounts receivable, product returns and Medicaid rebates are based primarily on our experience with Zevalin to date, historical experience with Rituxan and other factors, updated for changes in facts and circumstances, as appropriate. If actual results vary, we may need to adjust our estimates, which could have an impact on earnings in the period of adjustment.

Revenues from unconsolidated joint business arrangement consist of our share of the pretax copromotion profits generated from our copromotion arrangement with Genentech, reimbursement from Genentech of our Rituxan-related sales force and development expenses and royalty revenue from sales of Rituximab outside the United States by Roche and Zenyaku. Under the copromotion arrangement, all U.S. sales of Rituxan and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis, as defined in our collaborative agreement with Genentech. Pretax copromotion profits under the copromotion arrangement are derived by taking U.S. net sales of Rituxan to third-party customers less cost of sales, third-party royalty expenses, distribution, selling and marketing expenses and joint development expenses incurred by Genentech and us. Our profit-sharing formula with Genentech has two tiers; we earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We record our royalty revenue with a one-quarter lag.

Corporate partner revenues, which consist of contract revenues and license fees, are recognized in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, or SAB No. 101.

Revenue is not recognized unless collectibility is reasonably assured and the earnings process is complete. We believe our revenue recognition policies are in compliance with SAB No. 101.

Income taxes: In preparing our consolidated financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatment of items for tax and financial statement purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheet. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Our estimates of future taxable income are derived from, among other items, our estimates of future deductions related to stock options. In the event that actual results differ from our estimates or we adjust our estimates in future periods, we may need to establish a valuation allowance which could materially impact our financial position and results of operations.

*Inventories*: Inventories are stated at the lower of cost, determined by the first-in, first-out method, or market. If inventory costs were to exceed expected market value due to excess, obsolescence or unmarketability, we would record allowances for the difference between the cost and

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the market value. We have not recorded any such allowances as of December 31, 2002. Included in inventory are raw materials used in the production of clinical products which are recorded to research and development expense when consumed. Pre-launch production of Zevalin antibodies manufactured prior to FDA approval in February 2002 were recognized as research and development expenses.

## **Results of Operations**

*Product Sales:* Product sales consist solely of sales of Zevalin, our radioimmunotherapy product which was approved by the FDA for the treatment of certain B-cell NHLs in February 2002. Cost of sales as a percentage of product sales was 11% and primarily consists of contractual royalties owed on Zevalin sales. Pre-launch production of Zevalin antibodies manufactured prior to FDA approval in February 2002 were recognized as research and development expenses. Zevalin sales to date have solely consisted of Zevalin antibodies produced prior to FDA approval in February 2002. Had pre-launch production of Zevalin antibodies been recorded as inventory, cost of sales as a percentage of product sales would have been approximately 14%.

*Revenues from Unconsolidated Joint Business Arrangement:* Revenues from unconsolidated joint business arrangement for the years ended December 31, 2002, 2001 and 2000, consist of the following (table in thousands):

	2002		2001			2000
	Φ.	224 400	Φ.	220 64 4	Φ.	440.004
Copromotion profits	\$	324,498	\$	228,614	\$	113,221
Bulk Rituxan sales		_		_		2,078
Reimbursement of selling and development expenses		15,879		8,160		9,322
Royalty revenue on sales of Rituximab outside the U.S.,						
including royalties received directly from Roche		45,432		14,654		8,161
			_		_	
	\$	385,809	\$	251,428	\$	132,782

Under our agreement with Genentech, our pretax copromotion profit-sharing formula has two tiers. We earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We began recording our profit share at the higher percentage during the first quarter of both 2002 and 2001 compared to the beginning of the second quarter of 2000.

Rituxan net sales to third-party customers in the United States recorded by Genentech for 2002 amounted to \$1.08 billion compared to \$779.0 million in 2001 and \$424.3 million in 2000. The increase in 2002 and 2001 was primarily due to increased market penetration in treatments of B-cell NHLs and chronic lymphocytic leukemia and increases in the wholesale price of Rituxan effective March 2002, March 2001 and May 2000.

Our royalty revenue on sales of Rituximab outside the U.S. is based on Roche and Zenyaku's end-user sales and is recorded with a one-quarter lag. The increase in royalty revenues in 2002 is due to higher sales of Rituxan outside the U.S. resulting from increased penetration of foreign markets, including initial sales of Rituxan in Canada and Japan.

Corporate Partner Revenues: Corporate partner revenues totaled \$4.7 million in 2002 compared to \$21.2 million in 2001 and \$21.9 million in 2000. The decrease in corporate partner revenues in 2002 is primarily due to decreased research and development funding in 2002 under our collaborations with Taisho, resulting from the termination of our collaboration with Taisho in 2002, and Mitsubishi, partially offset by increased research and development funding under our collaboration with Seikagaku. Additionally, in 2001, we recognized a \$5.0 million payment received from Schering AG when the

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EMEA accepted for filing the submission of a MAA for approval of Zevalin in Europe and \$3.3 million of revenues resulting from the implementation of SAB No. 101. The decrease in corporate partner revenues in 2001 resulted primarily from decreased research and development funding under our collaborations with Schering AG and Taisho, partially offset by increased research and development funding under our collaboration with Mitsubishi and a \$2.0 million milestone payment received under our collaboration with Eisai. Contract revenues and license fees are, in part, dependent upon the achievement of certain research and development and commercialization objectives and, accordingly, may vary from year to year.

Manufacturing Costs: Manufacturing costs recorded in 2000 are related to the production of bulk Rituxan sold to Genentech and were recognized when Genentech accepted the bulk Rituxan inventory. No manufacturing costs were recorded in 2002 and 2001 due to the transfer of all worldwide manufacturing responsibilities for bulk Rituxan to Genentech in September 1999. The final lots of bulk Rituxan manufactured by us during the third quarter of 1999 were accepted by Genentech during the first quarter of 2000. Since the transfer of all worldwide manufacturing responsibilities for bulk Rituxan to Genentech, and prior to receiving FDA approval for Zevalin in February 2002, we used our manufacturing capacity for production of specification setting lots and commercial inventory of Zevalin antibodies and production of other proteins for clinical trials. Those manufacturing expenses were recorded as research and development expenses.

Research and Development Expenses: Research and development expenses totaled \$93.6 million in 2002 compared to \$86.3 million in 2001 and \$68.9 million in 2000. The increase in research and development expenses in 2002 is primarily due to upfront fees incurred under new collaborations, one-time license fees incurred for technology rights related to our products, increased personnel expenses and expansion of our facilities to support our ongoing basic research and clinical development programs, partially offset by capitalization of manufacturing costs for the production of commercial inventory of Zevalin antibodies and decreased clinical testing and development costs for Zevalin as a result of the FDA's approval of Zevalin. The increase in research and development expenses in 2001 is primarily due to increased clinical testing of our various products under development, development costs for Zevalin, personnel expenses and expansion of our facilities.

Our Zevalin bulk inventory levels at December 31, 2002 are expected to be adequate to support Zevalin sales in 2003. As such, we do not anticipate manufacturing Zevalin bulk inventory in 2003. In 2003, our manufacturing facilities will be primarily used to support products in development which will cause the majority of the costs of our manufacturing operations to be recorded as research and development expense in 2003. Such costs were capitalized into inventory in 2002 to the extent they related to the manufacture of Zevalin. In the future we expect to continue incurring substantial additional research and development expenses due to:

• preclinical and clinical testing of our various products under development;

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the expansion or addition of research and development programs;

- technology in-licensing;
- regulatory-related expenses;
- the expansion of clinical manufacturing capabilities; and
- facilities expansion.

Selling, General and Administrative Expenses: Selling, general and administrative expenses totaled \$95.2 million in 2002 compared to \$55.2 million in 2001 and \$27.8 million in 2000. Selling, general and administrative expenses in 2002 increased primarily due to increased sales and marketing expenses related to the commercial launch of Zevalin, sales expenses to support the commercialization of

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Rituxan, increased legal fees to protect our intellectual property rights for Zevalin and increases in general and administrative expenses to support overall organizational growth. Selling, general and administrative expenses increased in 2001 primarily due to increased marketing and administrative expenses related to the commercialization of Zevalin, sales expenses to support Rituxan, legal expenses to defend Zevalin patent issues and general increases in general and administrative expenses to support overall organizational growth. Selling, general and administrative expenses are expected to increase in the foreseeable future to support the following:

- marketing and administration related to the commercialization of Zevalin;
- manufacturing capacity expansion;
- clinical trials;
- research and development; and
- protection and enforcement of our intellectual property rights for Zevalin and our product candidates.

Interest Income/Expense: Interest income totaled \$33.7 million in 2002 compared to \$37.8 million in 2001 and \$20.5 million in 2000. The decrease in interest income in 2002 is primarily due to significantly lower interest rates earned on our cash, cash equivalents and securities available-for-sale, partially offset by higher cash balances from the issuance of our senior convertible promissory notes due 2032, or senior notes, in April and May 2002. The increase in interest income in 2001 is primarily due to higher average balances in cash, cash equivalents and securities available-for-sale resulting from the sale of 7.8 million shares of our common stock in November 2000, cash provided by operations and cash provided from the issuance of common stock under our stock option and purchase plans. The average yields earned on our investments in 2002 decreased from the average yields earned on our investments in 2001 as a result of declining market interest rates. Interest income levels to be achieved in the future are, in part, dependent upon market conditions.

Interest expense totaled \$16.1 million in 2002 compared to \$7.3 million in 2001 and \$7.1 million in 2000. The increase in interest expense in 2002 is due to noncash interest expense from our senior notes issued in April and May 2002, partially offset by the capitalization of \$0.4 million of interest costs related to the development of our corporate headquarters and research and development campus in San Diego, California and our large-scale manufacturing facility in Oceanside, California. The increase in interest expense in 2001 is primarily due to noncash interest from our subordinated convertible promissory notes due 2019, or subordinated notes, issued in February 1999.

Income Tax Provision: Our effective tax rate in 2002 was approximately 36% compared to 37% percent in 2001 and 17% in 2000. Our effective tax rates for 2002 and 2001 were less than a normal statutory rate due primarily to the generation of tax credits by our research and development activities. We have net operating loss and tax credit carryforwards for federal and state income tax purposes available to offset future taxable income. The utilization of our net operating loss carryforwards and tax credits may be subject to an annual limitation under the Internal Revenue Code due to a cumulative change of ownership of more than 50% in prior years. However, we anticipate this annual limitation to result only in a slight deferral in the utilization of our net operating loss carryforwards and tax credits. During 2002, we decreased our valuation allowance for deferred tax assets to zero as, based upon the level of historical taxable income and projections for future taxable income over the periods that our deferred tax assets are deductible, we believe it is more likely than not that we will realize the benefits of our deferred tax assets. In the event that actual results differ from our estimates of future taxable income or we adjust our estimates in future periods, we may need to establish a valuation allowance which could materially impact our financial position and results of operations. We expect that our effective tax rate in the future will be slightly higher than levels achieved in 2002 but continue to be

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lower than a normal statutory rate as a result of our continued research and development efforts which we expect to generate tax credits.

Cumulative Effect of Accounting Change: In the fourth quarter of 2000, we implemented SAB No. 101, which became effective as of January 1, 2000. SAB No. 101 provides that nonrefundable up-front fees received under collaborative agreements be recorded as deferred revenue upon receipt and recognized as revenue over future periods. Prior to the implementation of SAB No. 101, we recognized certain nonrefundable up-front fees as revenue upon receipt. The cumulative effect of this accounting change on years prior to 2000 resulted in a charge of \$9.3 million, net of a \$0.5 million income tax effect, of which \$3.3 million and \$6.5 million was recognized as license fee revenue in 2001 and 2000, respectively. This accounting change was directly related to the \$13.0 million up-front license fee received from Schering AG that was initially recognized as license fee revenue in 1999, prior to the implementation of SAB No. 101.

We have financed our operating and capital expenditures since inception principally through sales of equity securities, profits from our joint business arrangement related to the sale of Rituxan, corporate partner revenues, lease financing transactions, debt financing transactions and interest income. We expect to finance our current and planned operating requirements principally through cash on hand, which includes the proceeds from the April and May 2002 issuance of our senior notes, funds from our joint business arrangement, funds from commercial sales of Zevalin and funds from existing collaborative agreements and contracts. We believe that these funds will be sufficient to meet our operating requirements for the foreseeable future. Existing collaborative research agreements and contracts, however, could be canceled by the contracting parties. In addition, we may, from time to time, seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources. Additional funds may not be obtainable through these sources on acceptable terms if at all. If adequate funds are not obtainable from our joint business arrangement, commercial sales of Zevalin, operations or additional sources of financing, our business could be harmed. Our working capital and capital requirements will depend upon numerous factors, including:

- the continued commercial success of Rituxan;
- the commercial success of Zevalin;
- timing and expense of obtaining regulatory approvals;
- funding and timing of payments related to several material capital projects, including the development of our large scale manufacturing facility
  and corporate headquarters and research and development campus;
- the progress of our preclinical and clinical testing;
- fluctuating or increasing manufacturing requirements and research and development programs;
- levels of resources that we devote to the development of manufacturing, sales and marketing capabilities, including resources devoted to the marketing of Zevalin;
- technological advances;
- status of competitors;
- our ability to establish collaborative arrangements with other organizations; and
- working capital required to satisfy the put options related to our senior notes.

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Until required for operations, we invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, foreign and United States government instruments and other readily marketable debt instruments in accordance with our investment policy.

At December 31, 2002, we had \$1.4 billion in cash, cash equivalents and securities available-for-sale compared to \$866.6 million at December 31, 2001. Sources of cash, cash equivalents and securities available-for-sale during the year ended December 31, 2002 included \$696.0 million from the issuance of our senior notes in April and May 2002, \$179.2 million provided by operations and \$23.1 million from the issuance of common stock under employee stock option and purchase plans. Uses of cash, cash equivalents and securities available-for-sale during the year ended December 31, 2002 included \$165.9 million used to fund construction projects and purchase property and capital equipment and \$135.0 million used for the repurchase of common stock for treasury.

In April and May 2002, we raised through the issuance of our senior notes, approximately \$696.0 million, net of underwriting commissions and expenses of \$18.4 million. Simultaneously with the issuance of the senior notes, we used a portion of the proceeds to fund the repurchase of \$135.0 million of our outstanding common stock. The senior notes are zero coupon and were priced with a yield to maturity of 1.75% annually. We will pay contingent cash interest to the holders of these senior notes during any nine-month period commencing on or after April 30, 2007 if the average market price of the senior notes for a five-trading-day measurement period preceding such nine-month period equals 120% or more of the sum of the issue price and accrued original issue discount for such senior note. The contingent interest payable per senior note in respect of any quarterly period within such nine-month period where contingent interest is determined to be payable will equal the greater of (1) the amount of regular cash dividends paid by us per share on our common stock during that quarterly period multiplied by the then applicable conversion rate or (2) 0.0625% of the average market price of a senior note for the five-trading-day measurement period, we will pay contingent interest semiannually at a rate of 0.125% of the average market price of a senior note for the five-trading-day measurement period immediately preceding such nine-month period.

Upon maturity, the senior notes will have an aggregate principal face value of \$1.2 billion. Each \$1,000 aggregate principal face value senior note is convertible at the holder's option at any time through maturity into 7.1881 shares of our common stock at an initial conversion price of \$82.49. In addition, holders of the senior notes may require us to purchase all or a portion of the senior notes on April 29, 2005, 2007, 2012 and 2017 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable at our option in cash, our common stock or a combination thereof. In addition, if a change in control in our company occurs on or before April 29, 2007, holders may require us to purchase all or a portion of their senior notes for cash. We have the right to redeem all or a portion of the senior notes for cash at any time on or after April 29, 2007 at set prices.

We have an agreement with MDS Canada for the development and supply of the radioisotope yttrium-90 used with our Zevalin product. Under the terms of our agreement with MDS Canada, we are obligated to make periodic payments into an escrow account. These funds secure certain obligations we have under the agreement regarding minimum annual purchases of yttrium-90 and MDS Canada's establishment of a new facility to supply us with yttrium-90. As of December 31, 2002, we have paid \$22.5 million into this escrow fund.

In September 2001, we purchased approximately 42.6 acres of land in San Diego, California for approximately \$31.7 million in cash where we are building a corporate headquarters and research and development campus. The first phase of construction is expected to be completed in mid 2004 at an estimated total cost of \$177 million which will be funded from our working capital. As of December 31, 2002, we have invested approximately \$8.4 million in the construction of this campus.

In April 2001, we purchased a building in Oceanside, California to be used potentially for the manufacture of Zevalin bulk antibody, drug supply for certain of our clinical trials and drug supply for any potential product launches prior to 2005. Refurbishment of this facility was completed in the fourth quarter of 2002 at a total cost of approximately \$57 million which was funded with our working capital. We are currently performing validation activities in this facility.

In September 2000, we purchased a 60-acre site in Oceanside, California for approximately \$18.9 million in cash. In December 2002, we purchased an additional 27 acres of land at the Oceanside site for \$7.9 million in cash. We are building a large-scale manufacturing facility at this location, which we anticipate using to commercialize our products currently in clinical trials if they are approved by the FDA. This facility will allow us to better control the manufacture of our products, reducing our reliance on contract manufacturers, as well as reducing commercial supply risk. We anticipate the first phase of the new facility to be mechanically completed in 2004, followed by commissioning and validation in 2005 and 2006. Total costs of this facility upon completion are estimated to be \$400 million which will be funded from our working capital. As of December 31, 2002, we have invested approximately \$93.7 million in the construction of this large-scale manufacturing facility.

In February 1999, we raised through the issuance of our subordinated notes, approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million. The subordinated notes are zero coupon and were priced with a yield to maturity of 5.5% annually. Upon maturity, the subordinated notes will have an aggregate principal face value of \$345.0 million. Each \$1,000 aggregate principal face value subordinated note is convertible at the holders' option at any time through maturity into 40.404 shares of our common stock at an initial conversion price of \$8.36. We are required under the terms of the subordinated notes, following a change in control occurring on or before February 16, 2004, to purchase any subordinated note at the option of its holder at a price equal to the issue price plus accrued original issue discount to the date of purchase the subordinated notes on February 16, 2004, 2009 or 2014 at a price equal to the issue price plus accrued original issue discount to the date of purchase with us having the option to repay the subordinated notes plus accrued original issue discount in cash, our common stock or a combination thereof. We have the right to redeem the subordinated notes on or after February 16, 2004.

In connection with our research and development efforts, we have entered into various collaborative arrangements under which we may be obligated to pay royalties or milestone payments if product development is successful. It is not anticipated that the aggregate of any royalty or milestone obligations under these arrangements will be material to our operations.

In January 2003, we entered into a collaboration agreement with Biogen, under which we will collaborate on the development of three oncology therapeutics from Biogen's pipeline of early-stage product candidates, including IDEC-201. Under the terms of this agreement, we will initially be responsible for the development costs of the product candidates, until that time, if any, when Biogen exercises opt-in rights with respect to each specific product candidate. If Biogen exercises its opt-in rights for a specific product, we will share equally all subsequent costs and economic benefit related to that specific product with Biogen. If Biogen chooses not to exercise its opt-in rights, we will pay royalties to Biogen for future sales, if any, of the specific products.

## **Contractual Obligations**

We had future minimum lease payment obligations under our operating leases totaling \$56.7 million as of December 31, 2002.

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## Other

Historically, we have not utilized off-balance sheet arrangements or derivative financial instruments in our operating, investing and financing activities. Our transactions with our related parties, Genentech, Roche and Zenyaku, are disclosed in Note 8 to our consolidated financial statements.

#### **New Accounting Standards**

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or Statement No. 146. Statement No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Statement No. 146 requires that the initial measurement of a liability be at fair value. The provisions of Statement No. 146 generally are required to be applied prospectively after the adoption date to newly initiated disposal activities. Therefore, we cannot determine the potential effect that the adoption of Statement No. 146 will have on our consolidated financial statements in the future.

In November 2002, the EITF released Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Issue No. 00-21 addresses how to determine whether a revenue arrangement involving multiple deliverables contains more than one unit of accounting for the purposes of revenue recognition and how the revenue arrangement consideration should be measured and allocated to the separate units of accounting. Issue No. 00-21 applies to all revenue arrangements that we enter into after June 27, 2003. The adoption of this statement is not currently anticipated to have a material impact on our financial condition or results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34, or FIN No. 45. FIN No. 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of certain guarantees. The initial recognition and initial measurement provisions of FIN No. 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN No. 45 are effective for interim or annual periods ending after December 15, 2002. We have adopted the disclosure provisions of FIN No. 45 as of December 31, 2002.* 

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities, an interpretation of ARB No. 51*, or FIN No. 46. FIN No. 46 requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. Variable interest entities that effectively disperse risk will not be consolidated unless a single party holds an interest or combination of interests that effectively recombines risks that were previously dispersed. FIN No. 46 also requires enhanced disclosure requirements related to variable interest entities. FIN No. 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds

a variable interest that it acquired before February 1, 2003. We do not believe that the adoption of this accounting pronouncement will have a material impact on our financial statements.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to a variety of market risks, including changes in interest rates affecting the return on our investments and the cost of our debt.

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At December 31, 2002, we maintained a portion of our cash and cash equivalents in financial instruments with original maturities of three months or less. We also maintained an investment portfolio containing financial instruments in which the majority have maturities at purchase of greater than three months but less than 24 months. These financial instruments, principally comprised of corporate obligations and U.S. government obligations, are subject to interest rate risk and will decline in value if interest rates increase. A hypothetical ten percent change in interest rates during the year ended December 31, 2002, would have resulted in approximately a \$3.3 million change in pretax income. We have not used derivative financial instruments in our investment portfolio.

Our long-term debt totaled \$866.2 million at December 31, 2002 and was comprised solely of our senior notes which bear interest at a rate of 1.75% and our subordinated notes which bear interest at a rate of 5.5%. These long-term debt obligations bear interest at a weighed average interest rate of 2.4%. Due to the fixed rate nature of our convertible promissory notes, an immediate ten percent change in interest rates would not have a material effect on our financial condition or results of operations.

We are also exposed to market risk in that an increase in our stock price or an increase in interest rates may make conversion of the convertible promissory notes to common stock beneficial to the convertible promissory notes holder. Conversion of the convertible promissory notes would have a dilutive effect on our earnings per share and book value per common share.

## Item 8. Consolidated Financial Statements and Supplementary Data.

See Index to Consolidated Financial Statements and Schedule at page 60.

## Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

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## PART III

## Item 10. Directors and Executive Officers of the Registrant.

- (a) The section labeled "Election of Directors" contained in our Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2003 is incorporated herein by this reference.
- (b) The section labeled "Compliance with Section 16(a) of the Securities Exchange Act of 1934" contained in our Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2003 is incorporated herein by this reference.
  - (c) The information concerning our Executive Officers is set forth in Part I of this Form 10-K.

## Item 11. Executive Compensation.

The section labeled "Executive Compensation and Related Information" contained in our Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2003 is incorporated herein by this reference.

## Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The sections labeled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plans" contained in our Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2003 are incorporated herein by this reference.

## Item 13. Certain Relationships and Related Transactions.

The section labeled "Certain Relationships and Related Transactions" contained in our Proxy Statement for our Annual Meeting of Stockholders to be held on May 19, 2003 is incorporated herein by this reference.

#### Item 14. Controls and Procedures.

We performed an evaluation under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures within the 90-day period prior to the filing of this report. Based on that evaluation, our management, including our principal executive officer and principal financial officer, concluded that our disclosure controls and procedures are effective and provide for timely collection and evaluation of information that may need to be disclosed to investors. There have been no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of our evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

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## **PART IV**

#### Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K.

1) Consolidated Financial Statements and Schedule:

See Index to Consolidated Financial Statements and Schedule at page 60.

2) Exhibits:

The following exhibits are referenced or included in this Form 10-K.

THE	onowing exhibits are referenced of included in this Form To Te.
Exhibit Number	Description
1.1(19)	Purchase Agreement for \$300,000,000 Liquid Yield Option Notes due 2019 (Zero Coupon—Subordinated) dated as of February 9, 1999 between the Registrant and Merrill Lynch, Pierce, Fenner & Smith
	Incorporated.
3.1(20)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(1)	Bylaws of the Registrant.
3.3(27)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.
4.1	Reference is made to Exhibit 3.1.
4.2	Reference is made to Exhibit 3.2.
4.3(2)	1992 Amended and Restated Registration Rights Agreement of IDEC California.
4.4(1)	Specimen Common Stock Certificate of the Registrant.
4.5	Reference is made to Exhibit 10.46.
4.6(7)	1995 Registration Rights Agreement of the Registrant.
4.8(18)	Preferred Share Purchase Rights.
4.9(19)	First Amendment to the Preferred Share Purchase Rights Agreement, dated July 22, 1997.
4.10(19)	Indenture dated as of February 16, 1999 between the Registrant and Chase Manhattan Bank and Trust
	Company, National Association.
4.11	Reference is made to Exhibit 1.1
4.12(10)	Form of Registered Liquid Yield Option™ Note due 2019.
4.13(26)	Amended and Restated Rights Agreement dated as of July 26, 2001 between us and Mellon Investor
4.14(21)	Services LLC.
4.14(31)	Indenture, dated as of April 29, 2002, between IDEC Pharmaceuticals Corporation and JP Morgan Trust
4.15(31)	Company, N.A.  Registration Rights Agreement, dated as of April 29, 2002, between IDEC Pharmaceuticals Corporation
4.13(31)	and Merrill Lynch, Pierce, Fenner & Smith Incorporated.
4.16(31)	Form of Liquid Yield Option™ Note dated April 29, 2002.
10.1(32)	1988 Stock Option Plan of the Registrant, as amended and restated through October 22, 2002.
10.2(13)	Form of Notice of Grant.
10.3(32)	Form of Option Agreement.
10.4(12)	Letter Agreement between the Registrant and Genentech, Inc., dated May 21, 1996.
10.5(2)	401(k) Plan of the Registrant.
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10.6(2)	Form of acceleration of vesting letter agreement between the Registrant and certain officers.
10.7(2)+	License Agreement with Coulter Immunology, dated May 16, 1991.
10.8(3)	Lease Agreement between the Registrant and Torrey Sorrento, Inc., dated July 9, 1992.
` '	_

10.6(2)	Form of acceleration of vesting letter agreement between the Registrant and certain officers.
10.7(2)+	License Agreement with Coulter Immunology, dated May 16, 1991.
10.8(3)	Lease Agreement between the Registrant and Torrey Sorrento, Inc., dated July 9, 1992.
10.9(3)+	Collaborative Research and License Agreement between the Registrant and SmithKline Beecham p.l.c.,
	dated October 12, 1992.
10.10(3)	Investment Agreement between the Registrant and S.R. One, Limited, dated October 16, 1992.
10.11(17)	1995 Employee Stock Purchase Plan, as amended and restated through January 20, 1999.
10.12(4)+	Collaborative Development Agreement between the Registrant and Mitsubishi Pharma Corporation,
	formerly Mitsubishi-Tokyo Pharmaceuticals, Inc., formerly Mitsubishi Chemical Corporation, dated
	November 11, 1993.
10.14(29)	1993 Non-Employee Directors Stock Option Plan, as amended and restated through March 23, 2001.
10.15(6)+	Collaborative Development Agreement between the Registrant and Seikagaku Corporation dated
	December 27, 1994.
10.16(6)+	License Agreement between the Registrant and Seikagaku Corporation dated December 27, 1994.
10.27(6)	1994 Registration Rights Agreement.
10.28(6)	Investment Agreement between the Registrant, SmithKline Beecham p.l.c. and SmithKline Beecham

10.28(6) Investment Agreement between the Registrant, SmithKline Beecham p.l.c. and SmithKline Beecham Corporation, dated December 28, 1994.

10.29(7)	Master Definitions Agreement between the Registrant and Genentech. Inc.
10.30(7)+	Collaboration Agreement between the Registrant and Genentech. Inc., dated Ma
10.31(7)+	Expression Technology Agreement between the Registrant and Genentech. Inc.,
10.32(7)	Preferred Stock Purchase Agreement between the Registrant and Genentech. Inc

arch 16, 1995.

dated March 16, 1995.

c., dated March 16, 1995.

10.33(7)Option Agreement between the Registrant and Genentech, Inc., dated March 16, 1995.

10.34(7) Preferred and Common Stock Purchase Agreement between the Registrant and ML/MS Associates, L.P., dated March 16, 1995.

Amendment Agreement between the Registrant and SmithKline Beecham p.l.c., dated January 20, 1993. 10.35(9)+

10.36(9)+Modification of the Amendment Agreement between the Registrant and SmithKline Beecham p.l.c., dated June 14, 1993.

10.37(8) Special Stock Issuance Plan.

10.40(15) Collaborative Development Agreement between the Registrant and Eisai Co., Ltd. dated December 11, 1995

10.41(15) License Agreement between the Registrant and Eisai Co., Ltd. dated December 11, 1995.

License Agreement between the Registrant, Genentech, Inc., and Zenyaku Kogyo Co., Ltd. dated 10.42(15) November 30, 1995.

10.43(15) Development Agreement between the Registrant, Genentech, Inc., and Zenyaku Kogyo Co., Ltd. dated November 30, 1995.

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- Supply Agreement between the Registrant and Zenyaku Kogyo Co., Ltd. dated November 30, 1995. 10.44(15)
- Termination Agreement between the Registrant and Zenyaku Kogyo Co., Ltd. dated November 30, 1995. 10.45(15)
- 10.46(15) Amendment to the Development Agreement between the Registrant, Genentech, Inc., and Zenyaku Kogyo Co., Ltd. dated November 30, 1995.
- Amendment to Collaboration Agreement between the Registrant and Genentech, Inc., dated November 30, 10.47(15) 1995.
- 10.48(11) License Agreement between the Registrant and Chugai Pharmaceutical Co., Ltd., dated March 31, 1996.
- 10.49(14) Lease Agreement between the Registrant and All Spectrum Services, Inc., dated August 13, 1996.
- 10.50(1) Form of Indemnification Agreement for Officers and Directors.
- 10.51(16)+ 9-AC Asset Transfer Agreement between the Registrant, Pharmacia & Upjohn S.p.A. and Pharmacia & Upjohn Company, dated February 10, 1997.
- 10.52(19) Purchase Agreement for \$300,000,000 Liquid Yield Option™ Notes due 2019 (Zero Coupon— Subordinated) dated as of February 9, 1999 between the Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated.
- 10.53(19) Indenture dated as of February 16, 1999 between the Registrant and Chase Manhattan Bank and Trust Company, National Association.
- 10.54(21)+ Collaboration & License Agreement between the Company and Schering Aktiengesellschaft, dated June 9,
- 10.58(22)+ Amended and Restated Collaborative Research and License agreement between IDEC Pharmaceuticals Corporation and SmithKline Beecham p.l.c., dated February 29, 2000
- Purchase Agreement and Escrow Instructions dated August 31, 2000 between the Company and Ivey 10.62(24)+Ranch Development Company, LLC.
- Isotope Agreement between us and MDS Nordion Inc. as amended by a first amendment on January 21, 10.63(25) +2000 and a second amendment on March 16, 2001.
- 10.64(28) +Purchase and Sale Agreement and Escrow Instructions between San Dieguito Partnership, L.P. and IDEC Pharmaceuticals Corporation, dated July 17, 2001, and the First, Second and Third Amendments to the Purchase and Sale Agreement and Escrow Instructions dated August 17, 2001, August 24, 2001 and August 29, 2001, respectively.
- Supply Agreement between DSM Pharmaceuticals, Inc., formerly Catalytica Pharmaceuticals, Inc. and 10.65(28)+ IDEC Pharmaceuticals Corporation dated August 8, 2001.
- 10.66(28) +Collaborative Development Agreement between IDEC Pharmaceuticals Corporation and Mitsubishi Pharma Corporation, formerly Mitsubishi-Tokyo Pharmaceuticals, Inc., dated September 21, 2001.
- 10.67(28) Amended and Restated IDEC Pharmaceuticals Corporation Deferred Compensation Plan dated September 5, 2001.
- 10.68(30)\* Third Amendment to Agreement between MDS Canada Inc., MDS Nordion division, successor to MDS Nordion Inc. and IDEC Pharmaceuticals Corporation dated November 12, 2001.

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- 10.69(31)+ Addendum to Collaborative Development Agreement, dated March 22, 2002, between IDEC Pharmaceuticals Corporation and Seikagaku Corporation.
  - 10.70\* Commercial Supply Agreement between Baxter Pharmaceutical Solutions LLC and IDEC Pharmaceuticals Corporation dated June 1, 2002.
    - 12.1 Computation of Ratio of Earnings to Fixed Charges.
  - 22.1(2) Subsidiaries of the Company.
    - 23.1 Independent Auditors' Consent

- Confidential Treatment has been granted with respect to portions of this agreement.
- TM Trademark of Merrill Lynch & Co., Inc.
- (1)Incorporated by reference to exhibit filed with our Registration Statement on Form 8-B filed on June 2, 1997.
- (2) Incorporated by reference to exhibit filed with our Registration Statement on Form S-1, File No. 33-40756.
- (3)Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the year ended December 31, 1992.

Confidential Treatment has been requested with respect to portions of this agreement.

- (4) Incorporated by reference to exhibit filed with our Registration Statement on Form S-1, File No. 33-76080. (5) Incorporated by reference to exhibit filed with our Registration Statement on Form S-8, File No. 33-93794. (6)Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the year ended December 31, 1994. (7)
  - Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 1995.

  - (8) Incorporated by reference to exhibit filed with our Registration Statement on Form S-8, File No. 33-90738.
  - (9) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 1995.
  - (10)Incorporated by reference to exhibit 4.4 filed with our Registration Statement on Form S-3, File No. 333-85339. (11)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.
  - (12)Incorporated by reference to exhibit filed with our Registration Statement on Form 8-K, dated May 21, 1996.
  - (13)Incorporated by reference to exhibit filed with our Registration Statement on Form S-8, File No. 333-81625.
  - (14)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
  - (15)Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the year ended December 31, 1995.
  - (16)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.

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- (17)Incorporated by reference to exhibit 99.1 to our Registration Statement on Form S-8, File No. 333-65494.
- (18)Incorporated by reference to exhibit filed with our Registration Statement on Form 8-A, dated August 1, 1997.
- (19)Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 1998.
- (20)Incorporated by reference to exhibit filed with our Proxy Statement filed on November 4, 1999.
- (21)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 1999.
- (22)Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 1999.
- (23)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.
- (24)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 2000.
- (25)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
- (26)Incorporated by reference to exhibit 4.1 filed with our Registration Statement on Form 8-A, File No. 333-37128 dated July 27, 2001.

Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

- (27)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
- (28)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
- (29)Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 2000.
- (30)Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 2001.
- (31)Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
- Reports on Form 8-K. On November 29, 2002, we filed a current report of Form 8-K reporting that William R. Rohn, our President and Chief Operating Officer, informed us that he has established a nondiscretionary sales plan intended to comply with Rule 10b5-1 under the Securities Exchange Act of 1934 in order to gradually diversify his holdings. The sales plan takes effect December 4, 2002 and expires one year later. The sales plan provides for sales of up to 125,000 shares of our common stock per three month period depending on prevailing market prices. The maximum number of shares of our

common stock that can be sold under the sales plan is 300,000 shares.

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#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IDEC PHARMACEUTICALS CORPORATION

By: March 28, 2003 /s/ WILLIAM H. RASTETTER, PH.D. Date:

> William H. Rastetter, Ph.D., Chairman, and Chief Executive Officer

#### POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below does hereby constitute and appoint William H. Rastetter, Ph.D. and Edward M. Rodriguez, or either of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution, for him and his name, place and stead, in any and all capacities, to sign this report filed on Form 10-K and any and all amendments to said Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated.

Pursuant to the requirements the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Capacity Date Name

/s/ WILLIAM H. RASTETTER, PH.D.	Chairman and Chief Executive Officer (Principal Executive Officer)	March 28, 2003
William H. Rastetter, Ph.D.	,	
/s/ EDWARD M. RODRIGUEZ	Vice President, Finance and Controller (Principal Financial and Accounting Officer)	March 28, 2003
Edward M. Rodriguez	recounting officery	
/s/ HERBERT BOYER, PH.D.		
Herbert Boyer, Ph.D.	Director	March 28, 2003
/s/ ALAN B. GLASSBERG, M.D.		
Alan B. Glassberg, M.D.	Director	March 28, 2003
/s/ KAZUHIRO HASHIMOTO		
Kazuhiro Hashimoto	Director	March 28, 2003
/s/ FRANKLIN P. JOHNSON, JR.		
Franklin P. Johnson, Jr.	Director	March 28, 2003
/s/ ROBERT W. PANGIA		
Robert W. Pangia	Director	March 28, 2003
/s/ BRUCE R. ROSS		
Bruce R. Ross	Director	March 28, 2003
/s/ LYNN SCHENK		
Lynn Schenk	Director	March 28, 2003
/s/ WILLIAM D. YOUNG		
William D. Young	Director	March 28, 2003
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## CERTIFICATIONS

## I, William H. Rastetter, Ph.D., certify that:

- 1. I have reviewed this annual report on Form 10-K of IDEC Pharmaceuticals Corporation;
- 2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ WILLIAM H. RASTETTER, PH.D.

William H. Rastetter, Ph.D.

Chairman of the Board and Chief Executive Officer

(Principal Executive Officer)

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## I, Edward M. Rodriguez, certify that:

- 1. I have reviewed this annual report on Form 10-K of IDEC Pharmaceuticals Corporation;
- 2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date:
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

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#### IDEC PHARMACEUTICALS CORPORATION

#### INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND SCHEDULE

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\* All other financial statements schedules are omitted because they are not required or are not applicable, or because the required information is included in the consolidated financial statements or notes thereto.

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#### INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders IDEC Pharmaceuticals Corporation:

We have audited the accompanying consolidated balance sheets of IDEC Pharmaceuticals Corporation and subsidiaries as of December 31, 2002 and 2001, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2002. In connection with our audits of the consolidated financial statements, we have also audited the consolidated financial statement schedule II as listed in the accompanying Index. These consolidated financial statements and consolidated financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of IDEC Pharmaceuticals Corporation and subsidiaries as of December 31, 2002 and 2001, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related consolidated financial statement schedule when considered in relation to the basic consolidated financial statements taken as a whole presents fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

San Diego, California January 29, 2003

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**IDEC Pharmaceuticals Corporation and Subsidiaries** 

CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

		2002		2001		2000	
Revenues:							
Product sales	\$	13,711	\$	_	\$	_	
Revenues from unconsolidated joint business arrangement		385,809		251,428		132,782	
Corporate partner revenues		4,702		21,249		21,900	
	_						
Total revenues (including related party revenues of \$385,809, \$251,449 and \$132,782 in 2002, 2001 and 2000, respectively)		404,222		272,677		154,682	
Operating costs and expenses:							
Cost of sales		1,457		_			
Manufacturing costs		_		_		2,134	
Research and development		93,648		86,299		68,922	
Selling, general and administrative		95,241		55,241		27,767	
Sening, general and daministrative		35,211				27,707	
Total operating costs and expenses		190,346		141,540		98,823	
Total operating costs and expenses		150,540		141,540		30,023	
Income from operations		213,876		131,137		55,859	
Interest income		33,719		37,771		20,541	
Interest expense		(16,073)		(7,304)		(7,053)	
Income before income tax provision and cumulative effect of accounting change		231,522		161,604		69,347	
Income tax provision		83,432		59,945		11,939	
Income before cumulative effect of accounting change		148,090		101,659		57,408	
Cumulative effect of accounting change, net of income tax benefit of \$481 in 2000						(9,263)	
Net income	\$	148,090	\$	101,659	\$	48,145	
Basic earnings per share:							
Before cumulative effect of accounting change	\$	0.97	\$	0.67	\$	0.43	
Cumulative effect of accounting change		_		_		(0.07)	
	_		_		_		
Basic earnings per share	\$	0.97	\$	0.67	\$	0.36	
Diluted earnings per share:							
Before cumulative effect of accounting change	\$	0.85	\$	0.59	\$	0.36	
Cumulative effect of accounting change		_		_		(0.06)	
			_		_		
Diluted earnings per share	\$	0.85	\$	0.59	\$	0.30	
Shares used in calculation of earnings per share:							
Basic		153,086		150,756		134,880	
Diluted		179,634		181,481		159,310	
Pro forma amounts, assuming retroactive application of accounting change:  Net income	\$	148,090	\$	101,659	¢	57,408	
Earnings per share:	Þ	140,090	Ф	101,039	\$	37,406	
Basic	\$	0.97	\$	0.67	\$	0.43	
Diluted	\$	0.85	\$	0.59	\$	0.36	
Shares used in calculation of earnings per share:	Ψ	0.05	Ψ	0.00	Ψ	0.50	
Basic		153,086		150,756		134,880	
		_55,000		_55,755		_5 .,550	

See accompanying notes to consolidated financial statements.

179,634

Diluted

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# **IDEC Pharmaceuticals Corporation and Subsidiaries**

# CONSOLIDATED BALANCE SHEETS

D	ecember 31,
2002	2001

181,481

159,310

Years Ended December 31,

Current assets.			
Cash and cash equivalents	\$	350,129	\$ 425,999
Securities available-for-sale		437,645	197,824
Accounts receivable, net of allowances of \$732 and \$99 at December 31, 2002 and 2001,			
respectively		4,920	993
Due from related parties		100,288	67,651
Inventories		33,665	524
Deferred tax assets		27,675	8,771
Prepaid expenses and other current assets		23,288	7,052
Total current assets		977,610	708,814
Securities available-for-sale		660,091	242,784
Property and equipment, net		264,537	108,588
Deferred tax assets		85,197	66,761
Restricted cash		22,500	5,002
Investments and other assets		49,754	9,267
Total assets	\$	2,059,689	\$ 1,141,216
15.111 4.55-6.5		2,000,000	 1,1 11,210
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$	3,886	\$ 3,866
Accrued costs and expenses		51,607	27,616
Deferred revenue		732	2,307
Total current liabilities		56,225	33,789
Notes payable	_	866,205	135,977
Deferred rent		3,118	2,853
Other long-term liabilities		24,451	12,118
Commitments and contingencies  Stockholders' equity:  Convertible preferred stock, \$0.001 par value, 8,000 shares authorized; 36 shares and 48			
shares issued and outstanding at December 31, 2002 and 2001, respectively; \$5,875 and \$6,666 liquidation value at December 31, 2002 and 2001, respectively		_	_
Common stock, \$0.0005 par value, 500,000 shares authorized; 154,391 shares and 152,775 shares issued and outstanding at December 31, 2002 and 2001, respectively		78	76
Additional paid-in capital		977,672	840,232
Accumulated other comprehensive income		3,764	1,085
Retained earnings		263,176	115,086
		1,244,690	956,479
Less treasury stock, at cost; 2,209 shares at December 31, 2002		135,000	330,473
Total stockholders' equity		1,109,690	956,479
Total liabilities and stockholders' equity	\$	2,059,689	\$ 1,141,216
		. ,	. ,

ASSETS

Current assets:

See accompanying notes to consolidated financial statements.

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# IDEC Pharmaceuticals Corporation and Subsidiaries

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

# (In thousands)

	Convert	tible Preferre Stock		ımon Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Treasury Stock	Total Stockholders' Equity
Balance at December 31, 1999 Comprehensive income:	218	\$ -	— 128,016	6 \$ 6	4 \$ 195,175	\$ (543)	) \$ (34,718)	) \$	\$ 159,978
Net income	_				- –	_	48,145	_	48,145

Unrealized gains on securities available-for-sale, net of \$570 income tax effect	_	_	_	_	_	1,060	_	_	1,060
Total comprehensive income	_	_	_	_	_	_	_	_	49,205
Issuance of common stock under stock option and stock purchase plans, net Issuance of common stock from offering Issuance of common stock from	_ _	_ _	7,180 7,800	4	24,599 449,534	_	=	=	24,603 449,538
conversion of series A-1 and A-2 convertible preferred stock	(65)	_	3,870	1	_	_	_	_	1
Tax benefit from stock option and stock purchase plans					11,294				11,294
Balance at December 31, 2000	153		146,866	73	680,602	517	13,427	_	694,619
Comprehensive income:									
Net income Unrealized gains on securities available-for-sale, net of \$359 income	_	_	_	_	_	_	101,659	_	101,659
tax effect	_	_	_	_	_	568	_	_	568
Total comprehensive income	_	_	_	_	_	_	_	_	102,227
Issuance of common stock under stock option and stock purchase plans, net Issuance of common stock from	_	_	4,315	2	28,093	_	_	_	28,095
conversion of series A-1 and A-6 convertible preferred stock	(105)	_	1,594	1	_	_	_	_	1
Tax benefit from stock option and stock purchase plans	_	_	_	_	131,537	_	_	_	131,537
Balance at December 31, 2001	48		152,775	76	840,232	1,085	115,086		956,479
Comprehensive income:									
Net income Unrealized gains on securities		_	_		_	_	148,090	_	148,090
available-for-sale, net of \$1,945 income tax effect	_	_	_	_	_	2,679	_	_	2,679
Total comprehensive income	_	_	_	_	_	_	_	_	150,769
Issuance of common stock under stock option and stock purchase plans, net Issuance of common stock from	_	_	3,112	2	23,057	_	_	_	23,059
conversion of series A-2 convertible preferred stock	(12)	_	708	_	_	_	_	_	_
Issuance of common stock from conversion of notes payable due 2019	_	_	5	_	46	_	_	_	46
Repurchase of common stock for treasury, at cost	_	_	(2,209)	_	_	_	_	(135,000)	(135,000)
Tax benefit from stock option and stock purchase plans	_	_	_	_	114,337	_	_	_	114,337
Balance at December 31, 2002	36 \$	_	154,391	\$ 78	\$ 977,672	\$ 3,764	\$ 263,176	\$ (135,000)	\$ 1,109,690

See accompanying notes to consolidated financial statements.

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# **IDEC Pharmaceuticals Corporation and Subsidiaries**

# CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,						
		2002	2001			2000	
Cash flows from operating activities:							
Income before cumulative effect of accounting change	\$	148,090	\$	101,659	\$	57,408	
Adjustments to reconcile net income to net cash provided by operating activities:							
Cumulative effect of accounting change for revenue recognition		_		_		(9,263)	
Depreciation and amortization		10,156		6,306		4,739	
Non-cash interest expense		26,905		7,284		6,914	
Deferred income taxes and tax impact from stock options		74,415		60,431		11,294	
Gain on sales of securities available-for-sale		(2,779)		(1,726)		_	
Other		1,665		101		498	
Change in assets and liabilities:							
Accounts receivable, net		(3,927)		704		(387)	
Due from related parties		(32,637)		(25,898)		(18,099)	

	(22.141)			2 400
Inventories	(33,141)	_		2,400
Prepaid expenses and other assets	(27,434)			(2,507)
Restricted cash	(17,498)	(5,002)		_
Accounts payable	20	2,129		468
Accrued costs and expenses	24,628	9,987		3,237
Deferred revenue	(1,575)	(687)		4,494
Other long-term liabilities	12,333	648		786
Net cash provided by operating activities	179,221	154,314	_	61,982
Cash flows from investing activities:				
Purchases of securities available-for-sale	(1,501,404)	(670,892)		(346,633)
Sales of securities available-for-sale	544,139	227,293		4,218
Maturities of securities available-for-sale	297,086	354,759		178,883
Purchases of property and equipment	(165,904)	(67,380)		(31,431)
Increase in investments and other assets	(13,071)	(500)		_
			_	
Net cash used in investing activities	(839,154)	(156,720)		(194,963)
Cash flows from financing activities:				
Proceeds from issuance of notes payable, net	696,004	_		
Payments on notes payable	_	(743)		(1,513)
Purchase of common stock for treasury	(135,000)	` <u>_</u>		_
Proceeds from issuance of common stock, net	23,059	28,096		474,142
			_	
Net cash provided by financing activities	584,063	27,353		472,629
Net (decrease) increase in cash and cash equivalents	(75,870)	24,947		339,648
Cash and cash equivalents, beginning of year	425,999	401,052		61,404
1 0 0 1			_	
Cash and cash equivalents, end of year	\$ 350,129	\$ 425,999	\$	401,052
Supplemental disclosures of cash flow information-				
Cash paid during the year for:				
Interest	\$ —	\$ 21	\$	138
Income taxes	\$ 356	\$ 152	\$	230

See accompanying notes to consolidated financial statements.

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# ${\bf IDEC\ Pharmaceuticals\ Corporation\ and\ Subsidiaries}$

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except per share data and unless as otherwise noted)

# Note 1: Organization and Summary of Significant Accounting Policies

*Business:* We are primarily engaged in the research, development, manufacture and commercialization of targeted therapies for the treatment of cancer and autoimmune and inflammatory diseases.

*Principles of Consolidation:* The consolidated financial statements include our financial statements and those of our wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents: We consider all highly liquid investments with maturities at purchase of three months or less to be cash equivalents. Our cash equivalents as of December 31, 2002 and 2001 totaled \$339.0 million and \$406.0 million, respectively, and consist of money market accounts and marketable debt securities.

*Investments:* Our investments consist of marketable debt securities, which we have classified as available-for-sale, and investments in equity securities of certain private biotechnology companies. We carry our available-for-sale securities at fair value, based on quoted market prices, with unrealized gains and losses excluded from results of operations and reported as accumulated other comprehensive income, net of tax. The cost of available-for-sale securities sold is based on the specific identification method. We have established guidelines that maintain safety and liquidity in our available-for-sale portfolio. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

Our equity investments are accounted for under the cost method as we have a less than 20% ownership interest and do not have the ability to exercise significant influence. Under the cost method of accounting, our investments are carried at cost and are adjusted only for other-than-temporary declines in fair value, distributions of earnings and additional investments. We periodically evaluate whether the declines in the fair value of our equity investments are other-than-temporary. This evaluation consists of a review of qualitative and quantitative factors, such as the investee's financial condition, results of operations,

operating trends and other financial ratios. The evaluation also considers the implied value from any recent rounds of financing completed by the investee, market prices of comparable public companies, and general market conditions.

*Inventories*: Inventories are stated at the lower of cost, determined by the first-in, first-out method, or market. Cost includes materials, labor and manufacturing overhead costs. We periodically review our inventories for excess or obsolete inventory and will provide appropriate allowances and dispositions as necessary. Included in inventory are raw materials used in the production of clinical products which are recorded as research and development expense when consumed. Inventories consist of the following at December 31:

	2002	2	001
Raw materials	\$ 2,911	\$	524
Work in process	30,582		_
Finished goods	172		
	\$ 33,665	\$	524

Pre-launch production of Zevalin antibodies manufactured prior to FDA approval in February 2002 were recognized as research and development expenses.

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*Property and Equipment:* Property and equipment are stated at cost. Additions and improvements are capitalized and maintenance and repairs are expensed when incurred. Depreciation of equipment is calculated using the straight-line method over the estimated useful lives of the assets, generally ranging from three to ten years. Amortization of leasehold improvements is calculated using the straight-line method over the shorter of the lease term or the estimated useful lives of the assets. We capitalize U.S. Food and Drug Administration, or FDA, validation costs as part of the effort required to acquire, construct and install long-lived assets, including readying them for their intended use, and amortize such costs over the estimated useful life of the related asset.

Fair Value of Financial Instruments: We carry our cash and cash equivalents and securities available-for-sale at market value. The carrying amount of our accounts receivable, due from related parties, accounts payable and accrued costs and expenses are considered to be representative of their respective fair values due to their short-term nature. The carrying value of our notes payable approximate fair value because the underlying instruments bear interest at rates comparable to current rates offered for instruments of similar terms and risk.

Impairment of Long-Lived Assets: Long-lived assets to be held and used, including intangible assets, are reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

Revenue Recognition: Product sales consist solely of sales of Zevalin, our radioimmunotherapy product which was approved by the FDA for the treatment of certain B-cell non-Hodgkin's lymphomas, or NHLs, in February 2002. We have retained all United States marketing and distribution rights to Zevalin and have granted marketing and distribution rights outside the United States to Schering Aktiengesellschaft, or Schering AG. We recognize revenue from Zevalin product sales upon shipment and transfer of title and risk of loss to the customer. We record allowances for estimated uncollectible accounts receivable, product returns and Medicaid rebates at the time of sale. Our estimates for uncollectible accounts receivable, product returns and Medicaid rebates are based primarily on our experience with Zevalin to date, historical experience with Rituxan and other factors, updated for changes in facts and circumstances, as appropriate.

Revenues from unconsolidated joint business arrangement consist of our share of the pretax copromotion profits generated from our copromotion arrangement with Genentech, Inc., or Genentech, a related party, reimbursement from Genentech of our Rituxan-related sales force and development expenses, royalty revenue on sales of Rituximab outside the United States by F. Hoffmann-La Roche Ltd., or Roche, and Zenyaku Kogyo Co., Ltd., or Zenayku, both related parties, and through March 2000 revenue from bulk Rituxan sales to Genentech (see Note 8). Rituxan is the trade name in the United States, Canada and Japan for the compound rituximab. Outside the United States, Canada and Japan, rituximab is marketed as MabThera. In our notes to our consolidated financial statements, we refer to rituximab, Rituxan and MabThera collectively as Rituxan, except where otherwise indicated. Under the copromotion arrangement with Genentech, all U.S. sales of Rituxan and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis, as defined in our collaborative agreement with Genentech. Pretax copromotion profits under the copromotion arrangement are derived by taking the U.S. net sales of Rituxan to third-party customers less cost of sales, third-party royalty expenses, distribution, selling and marketing

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expenses and joint development expenses incurred by Genentech and us. Our profit-sharing formula with Genentech has two tiers; we earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We began recording our profit share at the higher percentage during the first quarter of both 2002 and 2001 and the beginning of the second quarter of 2000. We record our royalty revenue with a one-quarter lag. Revenue from bulk Rituxan sales was recognized when Genentech accepted the bulk Rituxan. Upon acceptance of bulk Rituxan by Genentech the right to return no longer existed and there were no further performance obligations related to bulk Rituxan. In September 1999, we transferred all worldwide manufacturing responsibilities for bulk Rituxan to Genentech.

Corporate partner revenues consist of contract revenues and license fees. Contract revenues consist of nonrefundable research and development funding under collaborative agreements with our corporate partners and other funding under contractual arrangements with other parties. Contract research and development funding generally compensates us for discovery, preclinical and clinical expenses related to the collaborative development programs for our products and is recognized at the time research and development activities are performed under the terms of the collaborative agreements. Amounts received under the collaborative agreements are nonrefundable even if the research and development efforts performed by us do not eventually result in a commercial

product. Contract revenues earned in excess of contract payments received are classified as accounts receivable, and contract research and development funding received in excess of amounts earned are classified as deferred revenue.

License fees consist of non-refundable up-front fees from the sale of product rights and nonrefundable product development milestone payments under collaborative agreements with our corporate partners. Nonrefundable up-front fees from the sale of product rights are recorded as deferred revenue upon receipt and recognized as revenue over future periods, generally the estimated product development period. Nonrefundable product development milestone payments are recognized upon the achievement of product development milestone objectives as stipulated in agreements with our corporate partners and are nonrefundable even if the achievement of the product development objectives does not eventually result in a commercial product. Product development milestone objectives vary in each of our agreements. The achievement of product development milestone objectives that may lead to the recognition of license fee revenues may include:

- the achievement of preclinical research and development objectives;
- the initiation of various phases of clinical trials;
- the filing of an Investigational New Drug application, or IND, Biological License Application, or BLA, or New Drug Application, or NDA;
- the filing of drug license applications in foreign territories; and
- obtaining United States or foreign regulatory product approvals.

Revenue is not recognized unless collectibility is reasonably assured and the earnings process is complete. We believe our revenue recognition policies are in compliance with Securities and Exchange Commission Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, or SAB No. 101.

*Manufacturing Costs*: Manufacturing costs consist of manufacturing costs related to the production of bulk Rituxan sold to Genentech through March 2000.

Research and Development: Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits, facilities costs, overhead costs, clinical trial and related clinical manufacturing costs, contract services and other outside

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costs. Research and development costs, including upfront fees and milestones paid to collaborative partners, are expensed as incurred.

Stock-Based Compensation: At December 31, 2002, we had three stock-based employee compensation plans that are described more fully in Note 9. We account for those plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, or APB Opinion No. 25, and related interpretations. Accordingly, no stock-based employee compensation is reflected in net income as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net income and earnings per share for the years ended December 31, 2002, 2001 and 2000 if we had applied the fair value recognition provisions of FASB Statement No. 123, Accounting for Stock-based Compensation, or Statement No. 123, as amended, to stock-based employee compensation.

	2002			2001		2000
Net income, as reported	\$	148,090	\$	101,659	\$	48,145
Deduct: Total stock-based employee compensation expense						
determined under the fair value based method for all awards,						
net of related tax effects		(54,662)		(40,309)		(36,829)
			_		_	
Pro forma net income	\$	93,428	\$	61,350	\$	11,316
Earnings per share:						
Basic—as reported	\$	0.97	\$	0.67	\$	0.36
Basic—pro forma	\$	0.61	\$	0.41	\$	80.0
Diluted—as reported	\$	0.85	\$	0.59	\$	0.30
Diluted—pro forma	\$	0.54	\$	0.36	\$	0.07

In December 2002, we adopted FASB Statement No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of SFAS No. 123*, or Statement No. 148. This statement provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. This statement also amends the disclosure requirements of Statement No. 123 and Accounting Principles Board Opinion No. 28, *Interim Financial Reporting*, to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We will implement the interim period disclosure requirements of Statement No. 148 effective January 1, 2003.

Income Taxes: Income taxes are accounted for under the asset and liability method where deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

*Earnings Per Share:* Basic earnings per share utilizes net income and excludes the dilutive effects of our stock options and other convertible securities. Diluted earnings per share utilizes net income adjusted for the after-tax amount of interest associated with convertible debt and includes the potential dilutive

outstanding during the period. All share and earnings per share amounts for the year ended December 31, 2000 have been restated to reflect our three-for-one stock split effected in January 2001.

	Years Ended December 31,							
		2002		2001		2000		
Numerator:								
Net income	\$	148,090	\$	101,659	\$	48,145		
Adjustments for interest, net of income tax effect		4,926		4,588		_		
			_		_			
Net income, adjusted	\$	153,016	\$	106,247	\$	48,145		
Denominator:								
Weighted-average common shares outstanding		153,086		150,756		134,880		
Effect of dilutive securities:								
Stock options		9,783		13,422		17,736		
Convertible preferred stock		2,829		3,364		6,694		
Convertible promissory notes due 2019		13,936		13,939	_			
Dilutive potential common shares		26,548		30,725		24,430		
Weighted-average shares and dilutive potential common shares		179,634	_	181,481	_	159,310		
Basic earnings per share	\$	0.97	\$	0.67	\$	0.36		
Diluted earnings per share	\$	0.85	\$	0.59	\$	0.30		

Excluded from the calculation of diluted earnings per share for the year ended December 31, 2002 were 5.9 million shares of common stock from the assumed conversion of our 30-year senior convertible promissory notes due 2032 and options to acquire 5.4 million shares of common stock because their effect was antidilutive. Excluded from the calculation of diluted earnings per share for the year ended December 31, 2001 were options to acquire 2.5 million shares of common stock because their effect was antidilutive. Excluded from the calculation of diluted earnings per share for the year ended December 31, 2000 were 13.9 million shares of common stock from the assumed conversion of our 20-year zero coupon subordinated convertible promissory notes due 2019, and options to acquire 0.2 million shares of common stock because their effect was antidilutive.

*Use of Estimates:* Our management has made a number of estimates and assumptions relating to the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent assets and liabilities in conformity with accounting principles generally accepted in the United States of America. On an on-going basis, we evaluate our estimates, including those related to revenue recognition and related allowances, inventory allowances, income taxes including the valuation allowance for deferred tax assets, valuation of long-lived assets and investments, and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results could differ from these estimates.

Segment and Geographic Information: We operate in one segment, which is the research, development, manufacture and commercialization of targeted therapies for the treatment of cancer and autoimmune and inflammatory diseases. The chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment.

All of our revenues are generated in the United States other than the royalties we earn from sales of Rituxan outside of the United States by Roche and Zenyaku (see Note 8).

Concentrations of Risk: Approximately 95%, 92% and 86% of our total revenues in 2002, 2001 and 2000, respectively, are derived from our joint business arrangement (see Note 8). Approximately

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78% of our net product sales revenue in 2002 and approximately 86% of our accounts receivable, net at December 31, 2002 relate to one customer.

We currently sell Zevalin primarily to distributors and radiopharmacies throughout the United States, perform ongoing credit evaluations of our customers' financial condition and extend credit without collateral. In 2002, we did not record any material additions to, or losses against, our allowance for doubtful accounts.

We have an agreement with MDS Canada, Inc., or MDS Canada, formerly MDS Nordion, Inc., to be our sole supplier of the radioisotope yttrium-90 that is required for the therapeutic use of Zevalin (see Note 11). Additionally, there are currently only two sources approved by the FDA to supply the indium-111 isotope required for the imaging use of Zevalin. Sales of Zevalin and our results of operations could be adversely affected by an interruption or reduction in the supply of yttrium-90 or indium-111.

We rely heavily upon third-party manufacturers to manufacture significant portions of Zevalin and our product candidates, particularly with respect to fill/finish services as we have no capacity in this area. While we could shift to alternative third-party manufacturers if necessary, our operations could be disrupted until alternative sources are secured.

Reclassifications: Certain reclassifications of prior year amounts have been made to conform with the current year presentation.

Cumulative Effect of Accounting Change: In the fourth quarter of 2000, we implemented SAB No. 101, which became effective as of January 1, 2000. SAB No. 101 provides that nonrefundable up-front fees received under collaborative agreements be recorded as deferred revenue upon receipt and recognized as revenue over future periods. Prior to the implementation of SAB No. 101, we recognized certain nonrefundable up-front fees as revenue upon receipt. The cumulative effect of this accounting change on years prior to 2000 resulted in a charge of \$9.3 million, net of a \$0.5 million income tax effect, of which \$3.3 million was recorded as deferred revenue as of December 31, 2000. During 2001 we recognized as revenue the full \$3.3 million of the related deferred revenue. The results for 2000 have been restated to reflect the adoption of SAB No. 101 as of January 1, 2000, which resulted in \$6.5 million being recognized as revenue in 2000.

New Accounting Pronouncement: In November 2002, the FASB issued FASB Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34, or FIN No. 45. FIN No. 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of certain guarantees. The initial recognition and initial measurement provisions of FIN No. 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN No. 45 are effective for interim or annual periods ending after December 15, 2002. We have adopted the disclosure provisions of FIN No. 45 as of December 31, 2002.

Our charter provides for indemnification, to the fullest extent permitted under Delaware law, of any person who is made a party to any action or threatened with any action as a result of such person's serving or having served as one of our officers or directors or having served, at our request, as an officer or director of another company. We have separate indemnification agreements with certain of our officers and directors. The indemnification does not apply if, among other things, the person's conduct is finally adjudicated to have been knowingly fraudulent or deliberately dishonest, or to constitute willful misconduct. The indemnification obligation survives termination of the indemnified party's involvement with us but only as to those claims arising from such person's role as an officer or

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director. The maximum potential amount of future payments that we could be required to make under the charter provision and the corresponding indemnification agreements is unlimited; however, we have director and officer insurance policies that, in most cases, would limit our exposure and enable us to recover a portion of any future amounts paid.

We also enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. However, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements.

#### Note 2: Securities Available-for-Sale

Securities available-for-sale at December 31 consist of the following:

	2002							
	A	mortized Cost	Gros	ss Unrealized Gains	Gro	oss Unrealized Losses	N	Aarket Value
Foreign debt:								
Current	\$	11,099	\$	73	\$	_	\$	11,172
Noncurrent		10,417		130		_		10,547
Corporate debt securities:								
Current		285,075		1,266		(92)		286,249
Noncurrent		312,670		1,985		(67)		314,588
Commercial paper:								
Current		20,486		299		_		20,785
Noncurrent		_		_		_		
U.S. government and state agencies:								
Current		118,726		713		_		119,439
Noncurrent		332,917		2,045	_	(6)		334,956
Total securities available-for-sale	\$	1,091,390	\$	6,511	\$	(165)	\$	1,097,736

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Amortized Cost	Gross Unrealized Gains	Gross Unrealized	Market Value

2001

2002

Foreign debt:							
Current	\$ 13,119	\$	111	\$	_	\$	13,230
Noncurrent	3,137		4		_		3,141
Corporate debt securities:							
Current	81,048		922		(5)		81,965
Noncurrent	190,878		1,131		(509)		191,500
Commercial paper:							
Current	16,928		5		_		16,933
Noncurrent	_		_		_		
U.S. government and state agencies:							
Current	85,609		101		(14)		85,696
Noncurrent	48,167		39		(63)		48,143
		_		_		_	
Total securities available-for-sale	\$ 438,886	\$	2,313	\$	(591)	\$	440,608

The amortized cost and estimated fair value of securities available-for-sale at December 31, 2002, by contractual maturity, are as follows:

	An	ortized Cost	Estimated Fair Value		
Due in one year or less	\$	435,386	\$	437,645	
Due after one year through two years		656,004		660,091	
	\$	1,091,390	\$	1,097,736	

#### **Note 3: Property and Equipment**

Property and equipment at December 31 consists of the following:

	2002			2001
Land	\$	58,879	\$	50,980
Furniture and fixtures		5,466		4,309
Machinery and equipment		52,167		33,527
Leasehold improvements		30,469		24,438
Construction in progress		159,139		26,962
		306,120		140,216
Accumulated depreciation and amortization		(41,583)		(31,628)
			_	
	\$	264,537	\$	108,588

During 2002, we capitalized to construction in progress a total of \$0.4 million of interest costs related to the development of our corporate headquarters and research and development campus in San Diego, California and our large-scale manufacturing facility in Oceanside, California.

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# **Note 4: Accrued Costs and Expenses**

Accrued costs and expenses at December 31 are as follows:

		2002		2001
		40.450	Φ.	==
Employee compensation and benefits	\$	12,473	\$	7,544
Clinical development expenses		2,528		3,089
Construction costs		17,082		5,891
Technology license and development fees		2,992		
Other		16,532		11,092
	_		_	
	\$	51,607	\$	27,616

# **Note 5: Notes Payable**

Notes payable at December 31 consist of the following:

	_	2002	2001		
20-year subordinated convertible promissory notes,	\$	143,408	\$	135,977	

due 2019 at 5.5%			
30-year senior convertible promissory notes,			
due 2032 at 1.75%	722,797		_
		_	
	\$ 866,205	\$	135,977

In April and May 2002, we issued 30-year senior convertible promissory notes, or senior notes, for gross proceeds of approximately \$714.4 million, or \$696.0 million net of underwriting commissions and expenses of \$18.4 million. Simultaneously with the issuance of the senior notes, we used a portion of the proceeds to fund the repurchase of \$135.0 million of our outstanding common stock. The senior notes are zero coupon and were priced with a yield to maturity of 1.75% annually. We will pay contingent cash interest to the holders of these senior notes during any six-month period commencing on or after April 30, 2007 if the average market price of the senior notes for a five-trading-day measurement period preceding such six-month period equals 120% or more of the sum of the issue price and accrued original issue discount for such senior note. The contingent interest payable per senior note in respect of any quarterly period within such six-month period where contingent interest is determined to be payable will equal the greater of (1) the amount of regular cash dividends paid by us per share on our common stock during that quarterly period multiplied by the then applicable conversion rate or (2) 0.0625% of the average market price of a senior note for the five-trading-day measurement period preceding such six-month period, provided that if we do not pay regular cash dividends during a semiannual period, we will pay contingent interest semiannually at a rate of 0.125% of the average market price of a senior note for the five-trading-day measurement period immediately preceding such six-month period.

Upon maturity, the senior notes will have an aggregate principal face value of \$1.2 billion. Each one thousand dollar aggregate principal face value senior note is convertible at the holder's option at any time through maturity into 7.1881 shares of our common stock at an initial conversion price of \$82.49, resulting in total potential common shares to be issued upon conversion of 8.7 million shares. In addition, holders of the senior notes may require us to purchase all or a portion of the senior notes on April 29, 2005, 2007, 2012 and 2017 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable at our option in cash, our common stock or a combination thereof. In addition, if a change in control in our company occurs on or before April 29, 2007, holders may require us to purchase all or a portion of their senior notes for cash. We have the

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right to redeem all or a portion of the senior notes for cash at any time on or after April 29, 2007 at set prices.

In February 1999, we raised approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million, through the issuance of 20-year subordinated convertible promissory notes, or subordinated notes. Upon maturity, the subordinated notes will have an aggregate principal face value of \$345.0 million. The subordinated notes were priced with a yield to maturity of 5.5% annually. Each one thousand dollar aggregate principal face value subordinated note is convertible at the holders' option at any time through maturity into 40.404 shares of our common stock at an initial conversion price of \$8.36 per share. We are required under the terms of the subordinated notes, as of 35 business days after a change in control occurring on or before February 16, 2004, to purchase any subordinated note at the option of its holder at a price equal to the issue price plus accrued original issue discount to the date of purchase. Additionally, the holders of the subordinated notes may require us to purchase the subordinated notes on February 16, 2004, 2009 or 2014 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable at our option in cash, our common stock or a combination thereof. We have the option to redeem the subordinated notes for cash any time on or after February 16, 2004.

#### **Note 6: Employee Benefit Plans**

401(k) Employee Savings Plan: We have a qualified 401(k) Employee Savings Plan, or 401(k) Plan, available to substantially all employees over the age of 21. We may make discretionary contributions to the 401(k) Plan in cash, which fully vest after four years of service by the employee. Discretionary contributions for the years ended December 31, 2002, 2001 and 2000 totaled \$1.8 million, \$0.8 million and \$0.6 million, respectively.

Deferred Compensation Plan: We have a Non-Qualified Deferred Compensation Plan that allows a select group of management and highly compensated employees to defer a portion of their compensation. The deferred compensation amounts and accumulated earnings are accrued but unfunded. Such deferred compensation is distributable in cash and at December 31, 2002 and 2001, amounted to approximately \$3.1 million and \$2.1 million, respectively, and is included in other long-term liabilities in the accompanying consolidated balance sheets. Participant contributions are immediately 100% vested. Distributions to participants can be either in a one-lump sum payment or annual installments as elected by the participants.

#### **Note 7: Research and Development Arrangements**

In September 2001, we entered into a collaborative development agreement with Mitsubishi Pharma Corporation, or Mitsubishi, formerly Mitsubishi-Tokyo Pharmaceuticals, Inc., to support clinical development of IDEC-114. Under the terms of an existing license agreement with Mitsubishi entered into in November 1993, Mitsubishi has an exclusive license in Asia to develop and commercialize anti-CD80 (anti-B7.1) antibody products. Under the terms of these agreements, we may receive milestone payments totaling up to \$22.0 million, subject to the attainment of product development objectives, as well as certain research and development support payments. Additionally, Mitsubishi will pay us royalties on sales of anti-CD80 (anti-B7.1) antibody products in its exclusive territories. Mitsubishi may terminate the license at any time upon 30 days' written notice, only after completion of Phase II clinical trials or for certain protocol changes in planned clinical trials for IDEC-114. During 2002 and 2001, we recognized revenues from our agreements with Mitsubishi of \$1.4 million and \$4.7 million, respectively, which are included in corporate partner revenues.

In June 2000, we entered into a collaborative research and development agreement with Taisho Pharmaceutical Co. Ltd. of Tokyo, or Taisho, to develop and commercialize antibody therapeutics against macrophage migration inhibitory factor, or MIF, for the treatment of inflammatory and

In June 1999, we entered into a collaboration and license agreement and a supply agreement with Schering AG aimed at the development and commercialization of Zevalin. Under the terms of the agreement, we may receive milestone and research and development support payments totaling up to \$47.5 million, subject to the attainment of product development objectives. Schering AG received exclusive marketing and distribution rights to Zevalin outside the United States, and we will receive royalties on product sales by Schering AG. Under the terms of a separate supply agreement, we are obligated to meet Schering AG's clinical and commercial requirements for Zevalin. Schering AG may terminate these agreements for any reason. During 2002, 2001 and 2000, we recognized revenues from our agreements with Schering AG of \$0.3 million, \$9.5 million and \$15.6 million, respectively, which are included in corporate partner revenues. Of the revenue recognized in 2001, \$6.0 million is for the attainment of product development objectives and a milestone payment when the European Medicines Evaluation Agency accepted for filing the submission of a MAA for approval of Zevalin in Europe. Additionally, as a result of implementing SAB No. 101, we recognized \$3.3 million and \$6.5 million of revenues in 2001 and 2000, respectively, which was previously recognized as revenue in 1999, prior to the implementation of SAB No. 101.

In December 1995, we entered into a collaborative development agreement and a license agreement with Eisai Co, Ltd., or Eisai, aimed at the development and commercialization of humanized and PRIMATIZED anti-CD40L antibodies. Under the terms of these agreements, we may receive milestone payments totaling up to \$12.5 million and research and development support payments totaling up to \$25.0 million, subject to the attainment of certain product development objectives and satisfaction of other criteria to be agreed upon between us and Eisai. Eisai received exclusive rights in Asia and Europe to develop and market products resulting from the collaboration, and we will receive royalties on product sales by Eisai. Eisai may terminate these agreements based on a reasonable determination that the products do not justify continued product development or marketing. During 2002 and 2001, we recognized revenues from our agreements with Eisai of \$0.7 million and \$2.2 million, respectively, which are included in corporate partner revenues. No revenues were recognized under our agreement with Eisai during 2000.

In December 1994, we entered into a collaborative development agreement and a license agreement with Seikagaku Corporation, or Seikagaku, aimed at the development and commercialization of a PRIMATIZED anti-CD23 antibody. Under the terms of these agreements, we may receive milestone and research and development support payments totaling up to \$26.0 million, subject to the attainment of product development objectives, as well as reimbursement for certain other research and development expenses incurred under our PRIMATIZED anti-CD23 antibody development program. Seikagaku received exclusive rights worldwide, except North, Central and South America, to all products resulting from the collaboration, and we will receive royalties on product sales by Seikagaku. Seikagaku may terminate these agreements based on a reasonable determination that the products do not justify continued product development or marketing. During 2002, we recognized revenues from our agreement with Seikagaku of \$1.6 million which are included in corporate partner revenues. No revenues were recognized under our agreement with Seikagaku during 2001 and 2000.

Under the above agreements, amounts earned by us and recognized as revenue for contract research and development approximate the research and development expenses incurred under the related agreement.

In connection with our research and development efforts, we have entered into various collaboration arrangements which provide us with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by the parties. Terms of the various license

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agreements may require us to make milestone payments upon the achievement of certain product development objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration. It is not anticipated that the aggregate of any royalty or milestone obligations under these arrangements will be material to our operations.

#### **Note 8: Related Party Transactions**

In March 1995, we entered into a collaborative agreement for the clinical development and commercialization of our anti-CD20 monoclonal antibody, Rituxan, for the treatment of certain B-cell non-Hodgkin's lymphomas with Genentech. Concurrent with the collaborative agreement, we also entered into an expression technology license agreement with Genentech for a proprietary gene expression technology developed by us, and a preferred stock purchase agreement providing for certain equity investments in us by Genentech (see Note 9). Under the terms of these agreements, we will be reimbursed by Genentech for certain development and regulatory approval expenses. Genentech may terminate the collaborative agreement for any reason, which would result in a loss of Genentech's Rituxan product rights. Due to its equity holdings in us and the significance of the joint business arrangement to our results of operations, Genentech is considered a related party.

In addition, we are copromoting Rituxan in the United States with Genentech under a copromotion arrangement whereby we receive a share of the pretax copromotion profits. Under the arrangement, we share responsibility with Genentech for selling and continued development of Rituxan in the United States. Continued development of Rituxan includes conducting supportive research on Rituxan, post approval clinical studies and obtaining potential approval of Rituxan for additional indications. Genentech provides the support functions for the commercialization of Rituxan in the United States including marketing, customer service, order entry, distribution, shipping and billing and, as of September 1999, all worldwide manufacturing responsibilities.

Under the terms of separate agreements with Genentech, commercialization of Rituxan outside the United States is the responsibility of Roche, except in Japan where it copromotes Rituxan in collaboration with Zenyaku. We receive royalties from Genentech on sales of Rituxan outside the United States, except Canada, by Roche and Zenyaku. Royalties on sales of Rituxan in Canada are received directly from Roche. Royalties received directly from Roche are included in revenues from unconsolidated joint business arrangement in the accompanying consolidated statements of income. Roche is the controlling stockholder of Genentech and therefore is considered a related party. Zenayku holds a seat on our Board of Directors and is one of our stockholders and therefore is considered a related party.

Revenues from unconsolidated joint business arrangement for the years ended December 31 consist of the following:

	_	2002		2001		2000
Copromotion profits	\$	324,498	\$	228,614	\$	113,221
Bulk Rituxan sales		_		_		2,078
Reimbursement of selling and development expenses		15,879		8,160		9,322
Royalty revenue on sales of Rituxan outside the U.S., including royalties received directly from Roche		45,432		14,654		8,161

#### Note 9: Stockholders' Equity

Convertible Preferred Stock: Our convertible preferred stock, which is held solely by Genentech, is convertible into shares of our common stock at anytime at the option of the holder. The terms of our convertible preferred stock and the number of issued and outstanding shares at December 31, 2002 are as follows:

Nonvoting Convertible Preferred Stock	Issue Date	Preferred Shares Issued And Outstanding	Liquidation erence Per Share	Common Conversion	
Series A-2	August 1995	13,221	\$ 67.00	60 shares	
Series A-3	March 1996	22,993	\$ 217.00	60 shares	

Stockholder Rights Plan: Effective July 26, 2001, our Board of Directors amended and restated the terms of our stockholder rights plan, originally adopted by the Board of Directors in 1997. Under the plan, we declared a dividend distribution of one "Right" for each outstanding share of our common stock to stockholders of record at the close of business on August 11, 1997. Since that time, we have issued one Right with each newly issued share of common stock. As amended, each Right, when exercisable, entitles the holder to purchase from us one one-thousandth of a share of our Series X Junior Participating Preferred Stock at a purchase price of \$500.00. In general, under the amended and restated plan, if a person or affiliated group acquires beneficial ownership of 15% or more of our shares of common stock, then each Right (other than those held by such acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Rights. In addition, if following the announcement of the existence of an acquiring person or affiliated group we are involved in a business combination or sale of 50% or more of our assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Rights. The Board of Directors also has the right, after an acquiring person or affiliated group is identified, to cause each Right to be exchanged for common stock or substitute consideration. We may redeem the Rights at a price of \$0.001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on July 26, 2011.

Stock Option Plans: We have two active stock option plans.

The 1988 Stock Option Plan, or the Option Plan, was approved by the stockholders in 1988 and has been subsequently amended. Under the Option Plan, options for the purchase of our common stock may be granted to key employees (including officers) and directors. Options may be designated as incentive stock options or as nonqualified stock options and generally vest over four years, except under a provision of the Option Plan which, under certain circumstances, allows accelerated vesting due to change in control events. Options under the Option Plan, which have a term of up to ten years, are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. The aggregate number of shares authorized for issuance under the Option Plan as of December 31, 2002 was 58.6 million shares.

In September 1993, we adopted the 1993 Non-Employee Directors Stock Option Plan, or the Directors Plan, which was approved by the stockholders in May 1994 and was subsequently amended. Options granted annually under the Directors Plan have a term of up to ten years and vest one year from the date of grant. The options are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. As of December 31, 2002, the aggregate number of shares authorized for issuance under the Directors Plan was 3.1 million shares.

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A summary of stock option activity is presented in the following table:

	Dir	ectors Plan	Option Plan			
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price		
Outstanding at December 31, 1999	1,177	\$ 5.57	22,953	\$ 4.91		
Granted	240	31.08	4,793	35.64		
Exercised	(339)	4.35	(6,781)	3.18		
Cancelled			(982)	14.27		
Outstanding at December 31, 2000	1,078	11.63	19,983	12.40		
Granted	155	61.07	3,825	56.03		
Exercised	(76)	19.05	(4,163)	6.11		
Cancelled			(824)	25.29		
Outstanding at December 31, 2001	1,157	17.76	18,821	22.08		
Granted	80	68.15	4,884	52.23		
Exercised	(96)	16.28	(2,919)	6.26		
Cancelled	(25)	62.80	(789)	43.43		
Outstanding at December 31, 2002	1,116	\$ 20.49	19,997	\$ 30.91		

				- Options	Exercisable
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 0.40 - \$ 3.50	2,726	2.78	\$ 2.29	9 2,726	\$ 2.29
3.75 - 9.51	5,749	5.49	6.9	7 5,626	6.92
13.73 - 31.08	1,687	7.12	22.2	3 1,196	22.29
34.00 - 48.78	5,734	8.56	42.5	3 1,734	38.09
51.60 - 68.15	5,217	8.53	60.0	1,997	59.03
\$ 0.40 - \$68.15	21,113	6.86	\$ 30.3	5 13,279	\$ 19.26

**Options Outstanding** 

At December 31, 2002, 2001, and 2000, options to purchase 13.3 million, 12.7 million, and 12.8 million shares, respectively, were exercisable at weighted average exercise prices of \$19.26, \$11.43, and \$6.33 per share, respectively.

*Employee Stock Purchase Plan:* In May 1993, the stockholders adopted our Employee Stock Purchase Plan, or the Purchase Plan, which was subsequently amended. As of December 31, 2002, a total of 1.0 million shares of our common stock were reserved for issuance. Under the terms of the Purchase Plan, employees can elect to have up to ten percent of their annual compensation withheld to purchase shares of our common stock. The purchase price of the common stock is at 85 percent of the lower of the fair market value of the common stock at the enrollment or purchase date. During 2002, 2001 and 2000, 0.1 million, 0.1 million and 0.1 million shares, respectively, were issued under the Purchase Plan.

*Pro Forma Information:* Pro forma information regarding net income and earnings per share, as disclosed in Note 1, has been determined as if we had accounted for our stock-based employee compensation plans under the fair value method prescribed by Statement No. 123. For pro forma disclosure purposes, the estimated fair value of stock-based compensation plans is amortized to expense over the vesting period using the straight-line method. The fair value of each option granted under the

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Option Plan and Directors Plan and the value of each purchase right granted under the Purchase Plan is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

Option Grants						
2002			2001		2000	
	0%		0%		0%	
	48.0%		50.0%		83.2%	
	2.7%		4.1%		5.1%	
	5.8		5.9		6.1	
\$	28.90	\$	29.10	\$	26.11	
		Pu	rchase Rights			
	2002		2001		2000	
	0%		0%		0%	
	48.0%		50.0%		83.2%	
	1.0%		5.0%		5.7%	
	0.3 - 2.0		0.3 - 2.0		0.3 - 2.0	
\$	19.73	\$	16.52	\$	14.08	
		0% 48.0% 2.7% 5.8 \$ 28.90  2002  0% 48.0% 1.0% 0.3 - 2.0	2002  0% 48.0% 2.7% 5.8 \$ 28.90 \$  Pu  2002  0% 48.0% 1.0% 0.3 - 2.0	2002 2001  0% 0% 48.0% 50.0% 2.7% 4.1% 5.8 5.9 \$ 28.90 \$ 29.10 Purchase Rights  2002 2001  0% 0% 48.0% 50.0% 1.0% 5.0% 0.3 - 2.0 0.3 - 2.0	2002 2001  0% 0% 48.0% 50.0% 2.7% 4.1% 5.8 5.9 \$ 28.90 \$ 29.10 \$  Purchase Rights  2002 2001  0% 0% 48.0% 50.0% 1.0% 5.0% 0.3 - 2.0 0.3 - 2.0	

#### **Note 10: Income Taxes**

The income tax provision for the years ended December 31 consists of the following:

		2002		2001		2000
Current:						
Federal	\$	65,653	\$	46,147	\$	14,624
State		14,414		11,284		6,148
	_		_			
Total current		80,067		57,431		20,772
	_		_		_	
Deferred:						
Federal		6,195		2,447		(7,125)
State		(2,830)		67		(1,708)
	_				_	
Total deferred		3,365		2,514		(8,833)
	_				_	
Total	\$	83,432	\$	59,945	\$	11,939
	_		_		_	

Income tax expense differed from the amounts computed by applying the U.S. federal income tax rate of 35% to pretax income as a result of the following for the years ended December 31:

	2002	2001	2000
Tax at U.S. federal statutory rate	35.0%	35.0%	35.0%
Change in valuation allowance	(0.8)	(0.2)	(18.6)
State taxes, net of federal benefit	3.2	4.5	4.2
Tax credits	(1.6)	(3.7)	(3.7)
Other	0.2	1.4	0.3
	36.0%	37.0%	17.2%

The tax benefits generated by our stock option and purchase plans, which were recorded to additional paid-in capital, were \$114.3 million, \$131.5 million and \$11.3 million in 2002, 2001 and 2000, respectively.

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The following table summarizes the tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities at December 31:

	_	2002	2001		
Deferred tax assets:					
General business credits	\$	107,946	\$	66,448	
Net operating loss carryforwards		5,610		60,800	
Capitalized state research and experimentation costs		5,343		3,829	
Intangibles, net		4,532		4,156	
Deferred revenue		1,828		1,577	
Expenses not currently deductible		6,262		5,271	
Other		582		4,605	
			_		
Gross deferred tax assets		132,103		146,686	
Valuation allowance		_		(70,732)	
			_		
Net deferred tax assets		132,103		75,954	
			_		
Deferred tax liabilities:					
Property and equipment		(2,719)		(136)	
Interest expense on notes payable		(13,930)		_	
Other		(2,582)		(286)	
	_		_		
Total deferred tax liabilities		19,231		422	
			_		
Total deferred taxes	\$	112,872	\$	75,532	

Our valuation allowance for deferred tax assets decreased \$70.7 million in 2002 and \$60.0 million in 2001, and increased \$73.2 million in 2000. The decrease in our valuation allowance for deferred tax assets in 2002 did not significantly affect our tax provision as the majority of the tax benefit resulting from the decrease in the valuation allowance was attributable to deferred tax assets generated by stock option deductions, primarily net operating loss carryforwards and tax credits. Accordingly, such tax benefit was recorded to additional paid-in capital.

As of December 31, 2002, we had net operating loss and general business credit carryforwards for federal income tax purposes of approximately \$11.9 million and \$95.9 million, respectively, which expire beginning in 2020 and 2012, respectively. Additionally, for state income tax purposes, we had net operating loss carryforwards of approximately \$25.0 million which expire beginning in 2007 and research and experimentation credit carryforwards of approximately \$18.2 million, which do not expire.

In assessing the realizability of our deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Our estimates of taxable income are derived from, among other items, our estimates of future deductions related to stock options. Based upon the level of historical taxable income and projections for future taxable income over the periods which the deferred tax assets are deductible, we believe it is more likely than not that we will realize the benefits of our deferred tax assets. Accordingly, in 2002, we decreased our valuation allowance for deferred tax assets to zero as of December 31, 2002. In the event that actual results differ from our estimates of future taxable income or we adjust our estimates in future periods, we may need to establish a valuation allowance which could materially impact our financial position and results of operations.

#### **Note 11: Commitments and Contingencies**

*Lease Commitments:* We lease various facilities and equipment under operating leases with original terms ranging from 3 to 15 years. We have the option to extend the terms of the leases for certain of our facilities for two consecutive periods of five years each. In addition to the monthly lease payments, the lease agreements provide for us to pay all operating expenses associated with the facilities. The lease agreements provide for scheduled rental increases; accordingly lease expense is recognized on a straight-line basis over the term of the leases.

Future minimum lease payments under all operating leases as of December 31, 2002 are as follows:

2003	\$ 9,223
2004	9,099
2005	9,399
2006	7,539
2007	7,586
2008 and thereafter	13,887
Total minimum lease payments	\$ 56,733

Lease expense under all operating leases totaled \$9.8 million, \$7.1 million and \$5.5 million for the years ended December 31, 2002, 2001 and 2000, respectively.

Supply and Escrow Agreement: In May 1999, we entered into an agreement with MDS Canada for the development and supply of the radioisotope yttrium-90 used with our Zevalin product, which we have subsequently amended. Under the terms of the agreement, as amended, MDS Canada has agreed to supply us, with certain exceptions, with the yttrium-90 required to meet the clinical and commercial needs in the United Sates and Canada for Zevalin and certain other products under development. The initial term of the agreement expires five years following commercialization of Zevalin. We have agreed to guarantee MDS Canada a minimum purchase level of yttrium-90 over the duration of the initial term of the agreement. In addition, MDS Canada has agreed to establish a new manufacturing facility to meet our yttrium-90 supply needs. Upon completion of this facility, MDS Canada can transition supply of yttrium-90 from its existing facilities to the new facility. To secure our minimum purchase commitments and in connection with MDS Canada's agreement to establish a new manufacturing facility, we have agreed to make periodic payments into an escrow account. As of December 31, 2002, we have paid \$22.5 million into this escrow fund. The agreement may be terminated by either party upon the bankruptcy of, or a material breach by, the other party. In addition, we can terminate the agreement following our satisfaction of the minimum purchase commitments, or earlier if we agree to forfeit a portion of the funds in the escrow account. Further, MDS Canada cannot terminate the agreement until five years following the date that its new manufacturing facility is established and capable of producing yttrium-90.

Legal Contingencies: On September 10, 2001, we filed a lawsuit in the federal district court in the Southern District of California against Corixa Corporation, formerly Coulter Pharmceuticals, Inc., or Corixa, and the University of Michigan seeking declaratory judgment that Zevalin and its use in the treatment of various B-cell non-Hodgkin's lymphomas does not infringe certain issued U.S. patents of Corixa regarding products and processes relating to radioimmunotherapy and a further declaration that Corixa's patents are invalid. On September 12, 2001, Corixa, GlaxoSmithKline, plc (Corixa's marketing partner), or Glaxo, and the University of Michigan filed a lawsuit in the federal district court in the District of Delaware against us for patent infringement. The lawsuit claims that we infringe the patents which are the subject of our declaratory judgment action against Corixa. The lawsuit seeks damages and to permanently enjoin us from commercializing Zevalin. This action has been transferred to San

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Diego and will be consolidated with our lawsuit. We cannot predict or determine the outcome of this litigation. An unfavorable outcome in this matter could limit our ability to sell Zevalin, could require us to pay damages for past sales of Zevalin and could require that we obtain a license from third parties to sell Zevalin. Any such unfavorable outcome could harm our business and our results of operations.

On September 10, 2001, we filed a second lawsuit in the federal district court in the Southern District of California against Glaxo seeking declaratory judgment that our manufacture of Zevalin does not infringe certain issued U.S. patents of Glaxo relating to cell culture media and further that Glaxo's patents are invalid. In November 2002, we settled the lawsuit and received a non-exclusive license under the Glaxo patents in exchange for payment of a lump-sum license

In addition, we are involved in certain other legal proceedings generally incidental to our normal business activities. While the outcome of any such proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any such existing matters would have a material adverse effect on our business or financial condition.

# Note 12: Quarterly Financial Data (unaudited)

		Year ended December 31, 2002							
	(	Quarter 1		Quarter 1 Quarter 2 Qu		Quarter 2 Quarter 3			Quarter 4
Total revenues	\$	79,741	\$	97,131	\$	103,698	\$	123,652	
Total operating costs and expenses		38,092		47,093		49,397		55,764	
Income from operations		41,649		50,038		54,301		67,888	
Net income	\$	29,673	\$	35,383	\$	38,440	\$	44,594	
Basic earnings per share	\$	0.19	\$	0.23	\$	0.25	\$	0.29	
Diluted earnings per share	\$	0.17	\$	0.20	\$	0.22	\$	0.26	
		Year ended December 31, 2001							
	(	Quarter 1		Quarter 2		Quarter 3		Quarter 4	

Total revenues	\$ 56,538	\$ 64,849	\$ 69,615	\$ 81,675
Total operating costs and expenses	33,174	33,121	33,742	41,503
Income from operations	23,364	31,728	35,873	40,172
Net income	\$ 20,807	\$ 25,153	\$ 26,957	\$ 28,742
Basic earnings per share	\$ 0.14	\$ 0.17	\$ 0.18	\$ 0.19
Diluted earnings per share	\$ 0.12	\$ 0.15	\$ 0.16	\$ 0.16

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#### **SCHEDULE II**

#### IDEC PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

# VALUATION AND QUALIFYING ACCOUNTS (In thousands)

Years Ended December 31, 2002, 2001 and 2000

Description	alance At ning Of Year	T	itions Charged to Costs And Expenses	 Deductions	Bal	lance At End Of Year
Allowance for doubtful accounts and returns:						
Year ended December 31, 2002	\$ 99	\$	1,129	\$ (496)	\$	732
Year ended December 31, 2001	\$ 353	\$		\$ (254)	\$	99
Year ended December 31, 2000	\$ 292	\$	854	\$ (793)	\$	353
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#### QuickLinks

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#### CONFIDENTIAL TREATMENT

#### COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement (this "Agreement") is entered into and effective as of the 1<sup>st</sup> day of June 2002 ("Effective Date") by and between Baxter Pharmaceutical Solutions LLC ("**BAXTER**"), a Delaware limited liability company having a place of business at 927 South Curry Pike, Bloomington, Indiana 47403, and IDEC Pharmaceuticals Corporation ("**CLIENT**"), a Delaware corporation having a place of business at 3030 Callan Road, San Diego, CA 92121.

#### RECITALS

- 1. CLIENT is engaged in the development, bulk production, formulation, sale and distribution of pharmaceutical products;
- 2. BAXTER is engaged in the filling, labeling and packaging of pharmaceutical products;
- 3. CLIENT and BAXTER desire to have BAXTER fill, package, inspect, label, and test a certain pharmaceutical product known as Ibritumomab Tiuxetan ("Zevalin") for distribution and sale by CLIENT.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree as follows:

#### **Article 1, DEFINITIONS**

As used in this Agreement, the following words and phrases shall have the following meanings:

- "Affiliate" of a party hereto shall mean any entity that controls or is controlled by such party, or is under common control with such party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of another entity (or other comparable ownership interest for an entity other than a corporation).
- 1.2 "Batch" shall mean a specific quantity of a Kit Component or Kit set forth in the Project Plan for such Kit Component or Kit that (a) is intended to have uniform character and quality within specified limits, and (b) is Produced according to a single manufacturing run during the same cycle of Production.
- 1.3 "BAXTER SOPs" shall mean BAXTER's Standard Operating Procedures. Copies of BAXTER's Standard Operating Procedures have been provided by BAXTER to CLIENT prior to the Effective Date. BAXTER shall be responsible at all times to cause the Product-specific BAXTER SOPs to be consistent with the Product Master Plan.
- 1.4 "BLA" shall mean CLIENT's biologics license application filed with the FDA relating to the Kit and each Kit Component, together with any amendments and supplements to such application as may be filed during the term of this Agreement.
- 1.5 **"Bulk Conjugated Antibody"** shall mean the bulk form of the active ingredient, 2B8-MX-DTPA conjugated antibody, used as the raw material in the Production of the Kit.
- "Cancellation Fee" shall be the applicable fee payable by CLIENT for modification or cancellation of a Firm Purchase Order set forth in [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time by mutual written agreement of the parties.

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- 1.7 "CLIENT Trademarks" shall mean the proprietary mark(s) for Product owned by CLIENT.
- "Components" shall mean all Components, including Bulk Conjugated Antibody, used by BAXTER in the Production of Products under this Agreement. Components are listed in the Kit Component Specifications and Kit Specifications, such Components identified as Components supplied by CLIENT ("CLIENT Supplied Components") and Components supplied by BAXTER ("BAXTER Supplied Components").
- 1.9 **"Confidential Information"** shall have the meaning set forth in the Confidentiality Agreement.
- 1.10 "Confidentiality Agreement" shall mean the Confidentiality Agreement signed by CLIENT and Baxter Healthcare Corporation on December 10, 2001 and assigned to BAXTER on or about January 1, 2002, as amended hereby and as amended, supplemented or restated hereafter from time to time by mutual written agreement of the parties.
- 1.11 "Current Good Manufacturing Practices" or "cGMP" shall mean (a) the good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA Regulations (including without limitation 21 CFR 210 and 211), policies or guidelines, in effect at any time during the term of this Agreement, for the Production and testing of pharmaceutical materials as applied solely to Products, and (b) the corresponding requirements of each applicable Regulatory Authority.
- 1.12 **"Delivery Date"** shall mean, (i) with respect to a Kit Component, the date that such Kit Component is filled, and (ii) with respect to a Kit, the date that such Kit is delivered to a common carrier designated by CLIENT.

- "Effective Date" shall mean the date of this Agreement as set forth above.
- 1.14 "FDA" shall mean the United States Food and Drug Administration or any successor entity thereto.
- 1.15 "FD&C Act" shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.
- 1.16 "**Kit**" shall mean one (1) reaction vial, one (1) 50mM sodium acetate vial, one (1) formulation buffer vial (U.S. or EU as applicable) and one (1) 2B8-MX-DTPA conjugated antibody vial, labeled, packaged and assembled with secondary packaging components for use either as an imaging agent (a "Labeled Imaging Kit") or as a therapeutic agent (a "Labeled Therapeutic Kit"), as specified in [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2.
- 1.17 **"Kit Component"** shall mean any one (1) of the individual vials specified in [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2, which is labeled ("Labeled Kit Component") or unlabeled ("Unlabeled Kit Component").
- 1.18 **"Kit Component Specifications"** shall mean the specifications and testing to be performed for each Kit Component, set forth on [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2.
- 1.19 **"Kit Specifications"** shall mean the specifications, and testing to be performed for each Kit, set forth on [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2.
- 1.20 **"Long Range Forecast"** shall be defined in Section 4.1.

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- "Master Batch Record" shall mean the formal set of instructions for the Production of each Kit Component or the Kit. The Master Batch Record for the Production of the 2B8-MX-DTPA conjugated antibody vial is set forth on [CONFIDENTIAL TREATMENT REQUESTED]. The Master Batch Record for each other Kit Component shall be the formal set of instructions, for the Production of such Kit Component, that is mutually acceptable to the parties and (except as the parties otherwise mutually agree in writing) shall contain all contents of the batch record previously provided by CLIENT to BAXTER for such Kit Component. The parties shall use commercially reasonable efforts to complete the Master Batch Record for each other Kit Component within [CONFIDENTIAL TREATMENT REQUESTED] after the Effective Date (but in any event prior to the Production of a Stability/Validation Batch for such Kit Component). The Master Batch Record for each other Kit Component shall be incorporated into [CONFIDENTIAL TREATMENT REQUESTED] upon their completion. The Master Batch Record for the Kits shall be the formal set of instructions, for the Production of the Kits, that is mutually acceptable to the parties and (except as the parties otherwise mutually agree in writing) shall contain all content of the batch record previously provided by CLIENT to BAXTER for the Kits. The parties shall use commercially reasonable efforts to complete the Master Batch Record for the Kits within [CONFIDENTIAL TREATMENT REQUESTED] after the Effective Date (but in any event prior to the Production of a Kit). The Master Batch Record for the Kits shall be incorporated into [CONFIDENTIAL TREATMENT REQUESTED] upon their completion. The Master Batch Record for each Kit Component or Kit may be amended, supplemented or restated from time to time by mutual written agreement of the parties.
- 1.22 "**Produce**" or "**Production**" shall mean the filling, packaging, inspecting, labeling, and testing of a Kit Component or Kit by BAXTER.
- 1.23 "**Products**" shall mean, collectively, the Kits and the Unlabeled Kit Components.
- 1.24 "**Product Master Plan**" shall mean, collectively, the following:
  - the Quality Agreement;
  - the Kit Specifications;
  - · the Kit Component Specifications;
  - the Master Batch Records;
  - · the Project Plans;
  - the Regulatory Authorities and Countries where Products will be sold, set forth on [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2;
  - the Regulatory Plan;
  - the Cancellation Fees;
  - the Purchase Prices; and
  - the Shipping Instructions.
- 1.25 **"Project Plans"** shall mean, collectively, the plans containing the parameters for the Production of Products set forth on [CONFIDENTIAL TREATMENT REQUESTED] 6, as amended, supplemented or restated from time to time by mutual written agreement of the parties.
- 1.26 "Purchase Order" shall mean written orders from CLIENT to BAXTER which shall specify (a) the quantity of Kit Component or Kit ordered,

- 1.27 "Purchase Price" shall mean, with respect to each Kit Component or Kit that is Produced under this Agreement and released by BAXTER's quality assurance department in accordance with the Quality Agreement, the applicable price for such Kit Component or Kit Produced under this Agreement set forth in Part A of [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing. The Purchase Price for each Kit Component or Kit is subject to adjustment from time to time in accordance with Section 5.3.
- 1.28 "Quality Agreement" shall mean the Intercompany Quality Agreement in the form attached as [CONFIDENTIAL TREATMENT REQUESTED] to this Agreement entered into by BAXTER and CLIENT as of the Effective Date, as amended, supplemented or restated from time to time in accordance with Section 2.3 or as the parties otherwise mutually agree in writing.
- 1.29 **"Regulatory Approval"** shall mean all authorizations by the appropriate Regulatory Authority necessary for commercial sale in a jurisdiction, including without limitation, approval of labeling, price, reimbursement and Production.
- 1.30 "Regulatory Authority" shall mean those agencies or authorities responsible for regulation of Products in the United States and overseas. BAXTER shall have no obligation to Produce Products in compliance with the requirements of a Regulatory Authority not specified in [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2.
- 1.31 "Regulatory Plan" shall mean the plan containing regulatory services and support for regulatory submissions and supporting documentation for Production of Products attached as [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time by mutual written agreement of the parties.
- 1.32 "Released Executed Batch Record" shall mean the completed batch record (in the form of the applicable Master Batch Record) and associated deviation reports, investigation reports, and Certificates of Analysis (provided in accordance with the Quality Agreement) created for each Batch and approved as released to CLIENT under cGMP by BAXTER's quality assurance department.
- 1.33 "Rolling Forecast" shall be defined in Section 4.1
- 1.34 "Shipping Instructions" shall mean the shipping instructions for Product Produced under this Agreement set forth on [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2.
- 1.35 "Stability/Validation Batches" shall mean (a) with respect to each Kit Component (other than the reaction vial specified in [CONFIDENTIAL TREATMENT REQUESTED] (as amended, supplemented or restated from time to time in accordance with Section 2.2.2)), the first [CONFIDENTIAL TREATMENT REQUESTED] cGMP batches thereof Produced under this Agreement, and (b) with respect to the reaction vial specified in [CONFIDENTIAL TREATMENT REQUESTED] (as amended, supplemented or restated from time to time in accordance with Section 2.2.2), the first cGMP batch thereof Produced under this Agreement.

#### Article 2, PRODUCT MASTER PLAN

2.1 **Product Master Plan.** Prior to the Effective Date, the parties have mutually agreed upon each of the exhibits attached to this Agreement comprising the Product Master Plan.

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#### 2.2 Amendment of Product Master Plan.

- 2.2.1 Except as otherwise set forth in Sections 2.2.2 and 2.3, the Product Master Plan may be amended from time to time, as the parties experience with the Production, testing and use of the applicable Product warrants, only upon mutual written agreement of CLIENT and BAXTER.
- At the reasonable request of CLIENT, the parties shall negotiate in good faith modification(s) to the Kit Specifications and/or Kit Component Specifications to address regulatory concerns raised by any Regulatory Authority or reasonably raised by CLIENT. At the reasonable request of CLIENT, the parties shall negotiate in good faith modification(s) to the list of countries where Products will be sold and/or the Regulatory Authorities. The Shipping Instructions may be amended from time to time, in the reasonable discretion of CLIENT effective upon written notice to BAXTER. In the event of any modification(s) to the Kit Component Specifications, Kit Specifications, the Shipping Instructions, the list of countries where Products will be sold and/or the Regulatory Authorities that result in an [CONFIDENTIAL TREATMENT REQUESTED]
- Quality Agreement. The effectiveness of this Agreement is conditioned upon the parties duly executing and delivering the Quality Agreement on or before the Effective Date. At the reasonable request of either party, the parties shall negotiate in good faith amendment(s) to the Quality Agreement (a) to address matters specific to the Production of Product for sale and use outside the United States, and (b) to address regulatory concerns raised by any Regulatory Authority or reasonably raised by either party.
- 2.4 **No Amendment of Agreement.** In the event that the terms of the Product Master Plan or Quality Agreement are inconsistent with the terms of this

Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the parties. The Product Master Plan and Quality Agreement shall be deemed to be incorporated herein and by reference and made a part of this Agreement.

#### Article 3, PURCHASE AND SUPPLY OF PRODUCT

- 3.1 **Agreement to Purchase and Supply.** Pursuant to the terms and conditions of this Agreement, CLIENT shall purchase from BAXTER, and BAXTER shall Produce and deliver to CLIENT, such quantities of Products as ordered by CLIENT in accordance with Sections 3 and 4 of this Agreement.
- Reproduction, Rework or Reprocessing. If any reprocessing, rework, or reproduction is required in order to meet the Kit Component Specifications and/or Kit Specifications, BAXTER shall conduct such reprocessing, rework, or reproduction in compliance with cGMPs and the BLA. Any reprocessing, rework, reproduction, or change which is not covered by the BLA must be approved in writing by CLIENT prior to implementation. [CONFIDENTIAL TREATMENT REQUESTED]

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- 3.3 **Bulk Conjugated Antibody and Other Components Delivery.** CLIENT, [CONFIDENTIAL TREATMENT REQUESTED], shall deliver or cause to be delivered, (a) a reasonably sufficient amount of Bulk Conjugated Antibody and/or other CLIENT Supplied Components, and (b) any applicable certificate of analysis therefor, all to be delivered to BAXTER at least [CONFIDENTIAL TREATMENT REQUESTED] calendar days in advance of the scheduled date for the applicable Production. Except as may specifically be set forth in the Product Master Plan, on receipt of the Bulk Conjugated Antibody and/or other CLIENT Supplied Components as set forth above, BAXTER's sole obligation with respect to evaluation of the Bulk Conjugated Antibody and other CLIENT Supplied Components (as applicable) conform with the Kit Specifications and/or Kit Component Specifications (as applicable). CLIENT at all times shall retain title to all Bulk Conjugated Antibody and other CLIENT Supplied Components, and all accompanying documentation supplied by CLIENT, together with all vials filled with Bulk Conjugated Antibody or other CLIENT Supplied Components.
- 3.4 **Material Safety**. CLIENT shall provide BAXTER a Material Safety Data Sheet for all Bulk Conjugated Antibody and other CLIENT Supplied Components delivered to BAXTER. BAXTER shall immediately notify CLIENT of any unusual health or environmental occurrence relating to a Product, including, but not limited to any claim or complaint by any employee of BAXTER or any of its Affiliates or third party that the operations of BAXTER pursuant to this Agreement have resulted in any adverse health or safety effect on an employee or third party. BAXTER agrees to advise CLIENT immediately of any safety or toxicity problems of which it becomes aware regarding a Product.
- 3.5 **Vendor and Supplier Audit and Certification**. CLIENT shall be solely responsible for certifying and auditing all vendors and suppliers of Bulk Conjugated Antibody and Components. All vendors and suppliers of Bulk Conjugated Antibody and Components shall be subject to CLIENT's prior written approval, and may be changed by CLIENT from time to time upon written notice to BAXTER. To the extent such changes result in increased cost to BAXTER, BAXTER may adjust the Purchase Price for Product in accordance with the mechanism set forth in Section 5.3.
- Purchase of Materials. BAXTER shall purchase, at BAXTER's expense, all packaging and filling materials listed in the Product Master Plan, primary container Components and secondary packaging materials required to Produce Product. BAXTER shall control packaging materials listed in the Product Master Plan and shall assist CLIENT with evaluation and purchase of modified materials in the event that CLIENT requests, pursuant to Section 2.2, a packaging change in the Kit Specifications and/or Kit Component Specifications. BAXTER shall not initiate any changes to materials without written approval from CLIENT.
- 3.7 **BAXTER Supplied Components.** BAXTER will purchase the BAXTER Supplied Components in quantities sufficient to meet CLIENT's Purchase Orders for Kit Components or Kits consistent with Section 4. [CONFIDENTIAL TREATMENT REQUESTED]
- 3.8 **Importer of Record.** In the event any material or equipment to be supplied by CLIENT, including without limitation CLIENT Supplied Components and Bulk Conjugated Antibody, is imported into the United States for delivery to BAXTER ("Imported Goods"), such Imported Goods shall be imported [CONFIDENTIAL TREATMENT REQUESTED] CLIENT shall be the "Importer of Record" of such Imported Goods. As the Importer of Record, CLIENT shall be responsible for (a) [CONFIDENTIAL TREATMENT REQUESTED], (b) [CONFIDENTIAL TREATMENT REQUESTED] (c) [CONFIDENTIAL TREATMENT REQUESTED].

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#### 3.9 Storage.

- 3.9.1 **Product Storage.** In no event shall BAXTER be required to store any Kit Component or Kit for more than [CONFIDENTIAL TREATMENT REQUESTED] after such Kit Component or Kit is released by BAXTER's quality assurance department, without BAXTER's prior written consent and CLIENT's agreement to reimburse BAXTER for at the rate set forth in Part B of [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing.
- 3.9.2 **Bulk Conjugated Antibody and Other CLIENT Supplied Component Storage**. In no event shall BAXTER be required to store more than a [CONFIDENTIAL TREATMENT REQUESTED] supply of Bulk Conjugated Antibody or other CLIENT Supplied Components as calculated [CONFIDENTIAL TREATMENT REQUESTED] without the prior written consent of BAXTER and CLIENT's agreement to reimburse BAXTER at the rate set forth in Part B of [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing.

3.9.3 **Third Party Storage.** BAXTER shall be permitted to store [CONFIDENTIAL TREATMENT REQUESTED] in third party storage facilities only to the extent permitted in the applicable Project Plans, provided in each case that (a) such third party shall have been previously approved in writing by CLIENT and (b) CLIENT shall have the right to visit, inspect and audit such third party's facilitates and records used in or that otherwise directly affect the storage of any Kit Component or Kit.

#### Article 4, [CONFIDENTIAL TREATMENT REQUESTED]

- 4.1 [CONFIDENTIAL TREATMENT REQUESTED].
  - 4.1.1 [CONFIDENTIAL TREATMENT REQUESTED].
  - 4.1.2 Prior to the [CONFIDENTIAL TREATMENT REQUESTED] of each [CONFIDENTIAL TREATMENT REQUESTED] after the Effective Date, CLIENT will provide BAXTER in writing a [CONFIDENTIAL TREATMENT REQUESTED] rolling forecast of CLIENT's forecasted orders for Products (the "Rolling Forecast"). CLIENT shall not increase the quantity forecasted for the [CONFIDENTIAL TREATMENT REQUESTED] of each Rolling Forecast to more than [CONFIDENTIAL TREATMENT REQUESTED] of the quantity forecasted for the second calendar quarter of the immediately preceding Rolling Forecast, and shall not decrease the quantity forecasted for the first calendar quarter of each Rolling Forecast to [CONFIDENTIAL TREATMENT REQUESTED] of the quantity forecasted for the [CONFIDENTIAL TREATMENT REQUESTED] of the immediately preceding Rolling Forecast.

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- 4.1.3 BAXTER shall supply CLIENT with the quantity of each Product ordered by CLIENT for a calendar quarter, unless the quantity ordered for such calendar quarter exceeds [CONFIDENTIAL TREATMENT REQUESTED] of the quantity of such Product forecasted for such calendar quarter in the most recent Rolling Forecast, in which event BAXTER shall use commercially reasonable efforts to supply quantities [CONFIDENTIAL TREATMENT REQUESTED] of the quantity of such Product forecasted for such calendar quarter in the most recent Rolling Forecast. In no event shall CLIENT order and purchase in any calendar quarter less [CONFIDENTIAL TREATMENT REQUESTED] of the quantity of such Product forecasted for such calendar quarter in the most recent Rolling Forecast (the "Minimum Quantity"). [CONFIDENTIAL TREATMENT REQUESTED] Notwithstanding anything to the contrary in this Agreement, CLIENT's minimum purchase obligations under this Agreement, other than with respect to the Stability/Validation Batches of Product under this Agreement, shall not commence [CONFIDENTIAL TREATMENT REQUESTED] Additionally, notwithstanding anything to the contrary in this Agreement, the [CONFIDENTIAL TREATMENT REQUESTED]
- 4.1.4 [CONFIDENTIAL TREATMENT REQUESTED]
- 4.2 **Purchase Orders.** Prior to or on the [CONFIDENTIAL TREATMENT REQUESTED], CLIENT shall submit Purchase Orders to BAXTER covering CLIENT's purchases of Kit Components and Kits pursuant to this Agreement. CLIENT shall not, without the written consent of BAXTER, designate (a) a Delivery Date in a Purchase Order for Kits earlier than [CONFIDENTIAL TREATMENT REQUESTED] from the date CLIENT submits the Purchase Order therefor, provided that CLIENT has satisfied its obligations under this Agreement to enable sufficient Kit Components to be available, or (b) a Delivery Date in a Purchase Order for Kit Components earlier than [CONFIDENTIAL TREATMENT REQUESTED] from the date CLIENT submits the Purchase Order. Within [CONFIDENTIAL TREATMENT REQUESTED]after the receipt of a Purchase Order, BAXTER shall provide a confirmation of receipt of such Purchase Order setting forth the Delivery Date that BAXTER will meet and setting forth BAXTER's filling date for such order. [CONFIDENTIAL TREATMENT REQUESTED] If BAXTER is unable to meet the specified Delivery Date, except when caused by CLIENT's delay in delivery of Bulk Conjugated Antibody or other CLIENT Supplied Components, BAXTER shall so notify CLIENT and provide to CLIENT an alternative Delivery Date which shall not be more than [CONFIDENTIAL TREATMENT REQUESTED] later than the initial Delivery Date designated by CLIENT in its Purchase Order. In the event that CLIENT modifies or cancels [CONFIDENTIAL TREATMENT REQUESTED] without BAXTER's written consent, CLIENT shall pay the Cancellation Fees as set forth in the Product Master Plan. To the extent of any conflict between Purchase Orders submitted by CLIENT and this Agreement, this Agreement shall control.
- 4.3 **Bulk Conjugated Antibody and Other Component Delivery Delays**. BAXTER shall have no responsibility for delays in delivery of Product caused by delays in receipt of Bulk Conjugated Antibody or other CLIENT Supplied Components. BAXTER shall have no responsibility for delays in delivery of Product to the extent [CONFIDENTIAL TREATMENT REQUESTED]

#### Article 5, PRICE

5.1 **Kit Component and Kit Purchase Price**. The price to be paid by CLIENT for each Kit Component or Kit that is Produced under this Agreement and released by BAXTER's quality assurance department in accordance with the Quality Agreement shall be the applicable Purchase Price therefor, as set forth in Part A of [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing.

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- 5.2 **Process Development, Validation, Regulatory and Other Services Price**. The price to be paid by CLIENT for process development, validation, regulatory and other services (which price shall exclude the Purchase Price for each Kit Component or Kit that is Produced under this Agreement and released by BAXTER's quality assurance department in accordance with the Quality Agreement) shall be set forth in Part B of [CONFIDENTIAL TREATMENT REQUESTED], as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing.
- 5.3 **Purchase Price Adjustment**. [CONFIDENTIAL TREATMENT REQUESTED], the Purchase Price of each Kit Component or Kit may be adjusted to reflect changes in the cost of BAXTER Supplied Components and labor costs paid by BAXTER in connection with the Production of such Kit

Component or Kit, not to exceed the change in the [CONFIDENTIAL TREATMENT REQUESTED]. BAXTER shall provide CLIENT with written notice, which notice shall set forth the amount of such Purchase Price adjustment. BAXTER shall provide such notice not later than [CONFIDENTIAL TREATMENT REQUESTED] following each such anniversary date to be effective, and any increase set forth in such notice shall be effective for Purchase Orders received by BAXTER after such anniversary date.

#### Article 6, SHIPMENT AND INVOICING

- Delivery Terms. BAXTER shall ship Products in accordance with the Product Master Plan, and deliver Products to CLIENT or to a location designated by CLIENT in applicable Purchase Order [CONFIDENTIAL TREATMENT REQUESTED] BAXTER's facility in Bloomington, Indiana freight collect, by a common carrier designated by CLIENT in Shipping Instructions, at [CONFIDENTIAL TREATMENT REQUESTED] expense; provided, however, subject to Article 13, BAXTER shall be responsible for the loading of Products on departure [CONFIDENTIAL TREATMENT REQUESTED] shall procure, [CONFIDENTIAL TREATMENT REQUESTED], insurance covering damage or loss to Products during shipping.
- 6.2 **Exporter of Record**. CLIENT shall be the exporter of record for any Product shipped out of the United States, as CLIENT remains the owner of such Product. CLIENT warrants that all shipments of any Product exported from the United States will be made in compliance with all applicable United States export laws and regulations and all applicable import laws and regulations into the country of deportation.
  - [CONFIDENTIAL TREATMENT REQUESTED]. CLIENT shall select and [CONFIDENTIAL TREATMENT REQUESTED] freight forwarder who shall solely be CLIENT's agent. CLIENT and its freight forwarder shall be responsible for preparing and filing the Shipper's Export Declaration and any other applications required for the export. BAXTER shall cooperate with CLIENT by providing reasonable assistance in preparing and filing any necessary documents to support CLIENT's import and export applications.
- 6.3 **Foreign Corrupt Practices Act.** CLIENT acknowledges it is not the agent of BAXTER and represents and warrants that it has not, and covenants that it will not, pay anything of value to any government employee in connection with the resale of Products.

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Payment Terms. BAXTER shall invoice CLIENT for each Kit Component or Kit that is Produced under this Agreement and released by BAXTER's quality assurance department in accordance with the Quality Agreement at the time such Kit Component or Kit is so released; provided, however, that the stated due date of each such invoice shall not be prior to the later of (a) [CONFIDENTIAL TREATMENT REQUESTED] following the date of CLIENT's receipt of the applicable Product samples, (b) [CONFIDENTIAL TREATMENT REQUESTED] following the date of CLIENT's receipt of the applicable Released Executed Batch Record(s) and related documentation in accordance with the Product Master Plan, or (c) [CONFIDENTIAL TREATMENT REQUESTED]s following the date of the invoice. BAXTER shall invoice CLIENT for all process development, validation and regulatory services (if any) monthly in arrears, which invoices shall set forth in reasonably specific detail the services performed and the costs therefor. CLIENT shall pay all amounts invoiced on or before the stated due date of the applicable invoice, provided that on the date of such invoice BAXTER shall have (a) sent by facsimile such invoice to CLIENT to such facsimile number as most recently requested in writing by CLIENT for such purpose, and (b) deposited the original of such invoice in the United States mail, first class postage prepaid and addressed to CLIENT at such address as most recently requested in writing by CLIENT for such purpose. Notwithstanding anything to the contrary in this Section, [CONFIDENTIAL TREATMENT REQUESTED]

Payments shall be made in U.S. dollars by check delivered to BAXTER, or by wire transfer. Each invoice shall be payable by CLIENT in accordance with the terms noted above. [CONFIDENTIAL TREATMENT REQUESTED].

6.5 **Default in Payment Obligations.** In addition to all other remedies available to BAXTER in the event of a CLIENT default, if CLIENT fails to make payments as required hereunder of amounts invoiced (other than amounts contested by CLIENT in good faith), [CONFIDENTIAL TREATMENT REQUESTED].

#### Article 7, ACCEPTANCE OF PRODUCT

- 7.1 **Product Conformity.** Within the later of [CONFIDENTIAL TREATMENT REQUESTED], CLIENT shall have the right to determine whether Product conforms to cGMP, to all other applicable United States laws and regulations and all foreign laws and regulations of the countries listed in [CONFIDENTIAL TREATMENT REQUESTED] (as amended, supplemented or restated from time to time in accordance with Section 2.2.2), to the applicable Kit Component Specifications and/or Kit Specifications, and to the applicable Project Plan(s) and the Quality Agreement (collectively the "Product Requirements"). Notwithstanding the foregoing, if CLIENT has conducted at least one test of the applicable Batch and in good faith has requested in writing, within the time period specified in Section 7.1, additional time to perform additional testing, then such period shall be extended as reasonably necessary for CLIENT, or BAXTER (if requested by CLIENT), to perform such additional testing.
  - 7.1.1 If (a) any Product conforms to the Product Requirements, or (b) CLIENT fails to notify BAXTER within the time period specified in Section 7.1 that any Product does not conform to the Product Requirements, then CLIENT shall be deemed to have accepted such Product and waived its right to revoke acceptance.
  - 7.1.2 If CLIENT believes any Product does not conform to the Product Requirements, it shall give written notice to BAXTER specifying the manner in which such Product fails to meet the Product Requirements. Guidelines for resolving any disputed claims regarding conformity of Product are set forth in Section 7.1.3.

laboratory or consultant for resolution, whose determination of conformity or non-conformity, and the cause thereof of non-conformity, shall be binding upon the parties. The non-prevailing party shall bear the costs of such laboratory or consultant, except as set forth in Section 7.2.3.

#### 7.2 Remedies for Non Conforming Product.

- 7.2.1 In the event BAXTER agrees that any Product is non-conforming or the laboratory determines that the shipment of Product is non-conforming, BAXTER shall replace such non-conforming Product within the latter of (a) [CONFIDENTIAL TREATMENT REQUESTED] from receipt of the applicable replacement CLIENT Supplied Component(s) from CLIENT or (b) [CONFIDENTIAL TREATMENT REQUESTED] from the date of determination by the third party of non-conformity or agreement by BAXTER of such non-conformity.
- 7.2.2 [CONFIDENTIAL TREATMENT REQUESTED]
- 7.2.3 [CONFIDENTIAL TREATMENT REQUESTED]
- 7.3 **Non Conforming Bulk Conjugated Antibody or Other CLIENT Supplied Components.** If Product is rejected by CLIENT, and such Product's failure to meet the Product Requirements is the result of non-conforming Bulk Conjugated Antibody or other CLIENT Supplied Component(s), then such non-conformity shall be deemed not to be non-conforming as a result of the negligence, omission or willful misconduct of BAXTER or BAXTER's breach of its warranties or obligations under this Agreement.

#### Article 8, TERM AND TERMINATION

- 8.1 **Term**. This Agreement shall be effective on the Effective Date and shall continue for sixty (60) months thereafter (the "Term"), unless earlier terminated in accordance with the terms of this Agreement.
- 8.2 **Termination for Breach.** Either party may terminate this Agreement upon the material breach of this Agreement by the other party if such material breach is not cured by the breaching party within ten (10) calendar days for monetary defaults, and thirty (30) calendar days for non-monetary defaults (or such additional time reasonably necessary to cure such non-monetary default provided the breaching party has commenced a cure within the thirty (30) calendar day period and is diligently pursuing completion of such cure) after receipt by the breaching party of written notice of such default. In the event that the Production or sale of any Product is enjoined due to the alleged infringement by either party of the proprietary rights of a third party such occurrence shall not be deemed a breach of this Agreement by CLIENT or BAXTER.
- Regulatory Approval to sell Product Produced by BAXTER under this Agreement within [CONFIDENTIAL TREATMENT REQUESTED] following the Effective Date due in whole or in part to any act or omission of BAXTER, or (b) upon the withdrawal of the Kit from the market and termination of the marketing and sales of the Kit by CLIENT.
- 8.4 **Additional Rights and Remedies.** Subject to Section 13.1, termination under this Section 8 shall be in addition to the other rights and remedies of the terminating party. Termination of this Agreement for any reason shall not relieve any party of any obligations accruing prior to such termination.

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- Non-cancelable Costs and Expenses. In the event of the termination of this Agreement, except by CLIENT as a result of a breach by BAXTER under Section 8.2, CLIENT shall (a) [CONFIDENTIAL TREATMENT REQUESTED] In addition, in the event of termination or cancellation for any reason, [CONFIDENTIAL TREATMENT REQUESTED] BAXTER promptly shall deliver such materials to CLIENT pursuant to Section 6.1. CLIENT shall make payment for all [CONFIDENTIAL TREATMENT REQUESTED] described in this Section 8.5 within thirty (30) calendar days from the date of receipt by CLIENT of the applicable invoice.
- 8.6 **Termination Damages.** In addition to [CONFIDENTIAL TREATMENT REQUESTED], (a) in the event of termination of this Agreement by BAXTER under Section 8.2 or (b) in the event of termination of this Agreement by CLIENT under clause (b) of Section 8.3, [CONFIDENTIAL TREATMENT REQUESTED].
- 8.7 **Survival.** Termination, expiration, cancellation or abandonment of this Agreement through any means or for any reason, except as set forth in Section 13.1, shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any of the provisions of this Agreement. The provisions of Sections 8, 12, 13, 14, 15, 16, 17 and 18 hereof shall survive expiration or termination of this Agreement.
- 8.8 **Files and Records**. Upon the expiration or termination of this Agreement, BAXTER promptly shall make available to CLIENT copies of all manufacturing and process development documents and records relating to Product, shall store the originals or electronic copies of such documents and records according to cGMPs in a safe and secure facility for at least two (2) years after the expiration date of the last Batch Produced by BAXTER under this Agreement, and shall permit the FDA or other Regulatory Authorities access to such documents and records to the extent requested thereby. For a period of twelve (12) months following expiration or termination of this Agreement, BAXTER shall make available to CLIENT for review, from the DMF, any non-confidential information contained therein that is reasonably related to Product that may be used by CLIENT to support any investigational studies or commercial marketing of Product.

#### Article 9, PRODUCTION OF PRODUCT

Production. BAXTER shall Produce Product in accordance with the Product Requirements. Subject to compliance with reasonable rules and regulations of BAXTER relating to confidentiality, safety and security, CLIENT shall have the right to access the BAXTER facilities directly affecting the Production of Product, and all applicable records related thereto, to oversee Production of Product in accordance with the Quality Agreement and BAXTER's standard visitation policy. CLIENT shall have the right to oversee each Production run of Product (from Component preparation through final labeling and assembly) in accordance with the Quality Agreement. CLIENT shall have the right to render technical advice and direction to BAXTER regarding Production of Product pursuant to their involvement in the generation of the Master Batch Record or direct communication with the Project Manager or

Technical Service Representative. BAXTER promptly shall implement all reasonable advice and direction provided that such advice and direction is not inconsistent with the Product Master Plan, BAXTER SOPs, and cGMPs. If CLIENT observes or discovers variances from established standards and methods of Production of Product, CLIENT shall give written notice thereof to BAXTER, and upon receipt of any such notice, BAXTER promptly shall take all appropriate remedial or corrective action and give written notice to CLIENT describing in reasonable detail such actions taken. If BAXTER disagrees with any such advice and direction, the parties shall discuss in good faith an appropriate resolution.

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- 9.2 Audits. CLIENT shall have the right to audit BAXTER's facilities in accordance with the Quality Agreement. Such audits shall be scheduled at mutually agreeable times upon reasonable advance written notice to BAXTER, shall be at CLIENT's expense, and shall not occur more than one (1) time per calendar year unless required by BAXTER's compliance status or CLIENT's obligations as a license holder. If CLIENT requests additional audits which are not due to BAXTER's compliance status and BAXTER agrees to such audits, CLIENT will incur fees as reasonably determined by BAXTER. Such fees shall be paid promptly upon completion of such audits. In connection with performing such audits, CLIENT shall comply with all reasonable rules and regulations promulgated by BAXTER relating to confidentiality, safety and security. All information disclosed or reviewed in such inspections shall be deemed to be the property of BAXTER and BAXTER Confidential Information (subject to the exceptions set forth in Section 1 of the Confidentiality Agreement).
- 9.3 **Testing.** In accordance with the Quality Agreement, BAXTER shall test, or cause to be tested by third party testing facilities audited by BAXTER, in accordance with the Product Requirements, each Batch of Product Produced pursuant to this Agreement before delivery to CLIENT. A certificate of analysis for each Batch of Product delivered to CLIENT shall set forth the items tested by BAXTER, specifications, and test results in accordance with the Quality Agreement. BAXTER shall send, or cause to be sent, such certificates along with one (1) copy of the Released Executed Batch Record to CLIENT prior to or at the same time of shipment of Product to CLIENT.

As required by the FDA, CLIENT shall assume full responsibility for final release of each lot of Product.

- Permits and Licenses. Client shall have sole responsibility, at its expense, for obtaining all permits and licenses necessary or required for the sale, marketing and commercialization of each Product Produced by BAXTER hereunder. BAXTER shall be responsible, [CONFIDENTIAL TREATMENT REQUESTED], to obtain and maintain all permits and licenses required for it to carry out its regulatory and Production obligations hereunder. BAXTER, at CLIENT's request [CONFIDENTIAL TREATMENT REQUESTED], shall cooperate with CLIENT by assisting in preparing and filing any necessary documents to support CLIENT's applications for permits and licenses.
- 9.5 **Regulatory Requirements**. Each party promptly shall notify the other of new regulatory requirements of which it becomes aware which are relevant to the Production of a Product under this Agreement and which are required by the FDA, any other applicable Regulatory Authority or other applicable laws or governmental regulations, and shall confer with each other with respect to the best means to comply with such requirements. Notwithstanding anything to the contrary in this Agreement, BAXTER shall be responsible for its compliance with all regulatory requirements of the United States and all foreign countries listed in [CONFIDENTIAL TREATMENT REQUESTED] (as amended, supplemented or restated from time to time in accordance with Section 2.2.2) that are applicable to BAXTER's facilities and BAXTER's activities in Production, whether or not CLIENT is aware of such requirements and has failed to give notice to BAXTER.
- 9.6 **Drug Master File**. In accordance with the Product Master Plan, BAXTER shall file and maintain the appropriate Drug Master File ("DMF") and related reference applications (e.g. Site Master File) for its Production of each Product hereunder in accordance with 21 CFR 314.420, as may be amended from time to time, at BAXTER's expense.

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## 9.7 Changes in Manufacturing

- 9.7.1 Changes to Product Master Plan. BAXTER agrees to inform CLIENT within [CONFIDENTIAL TREATMENT REQUESTED] of the result of any regulatory development that directly affect the Production of a Product or changes to Product-specific BAXTER SOPs. BAXTER shall give written notice to CLIENT of any such changes, and CLIENT and BAXTER will review such development or changes in accordance with the Quality Agreement; provided, however, that (a) BAXTER shall assure that all such changes to the Product-specific BAXTER SOPs are consistent with the Product Master Plan unless the parties otherwise expressly agrees in writing, and (b) any changes to the Product Master Plan shall be made only in accordance with Section 2.2.
- 9.7.2 **Product-Specific Changes**. If facility, equipment, process or system changes are required of BAXTER as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply primarily to the Production and supply of a Product, then CLIENT and BAXTER will review such requirements and agree in writing to such regulatory changes in accordance with the Quality Agreement, and [CONFIDENTIAL TREATMENT REQUESTED] (a) BAXTER shall assure that all such changes to the Product-specific BAXTER SOPs are consistent with the Product Master Plan unless the parties otherwise expressly agree in writing, and (b) any changes to the Product Master Plan shall be made only in accordance with Section 2.2.
- 9.8 **Equipment Expenses.** If BAXTER is required to obtain specialized equipment in order to Produce a Product for CLIENT, the costs of such equipment [CONFIDENTIAL TREATMENT REQUESTED].
- 9.9 **Ownership and Use of Equipment**. All such equipment [CONFIDENTIAL TREATMENT REQUESTED] shall be owned solely by CLIENT; provided, however, that such equipment shall remain at BAXTER's facility used for Production of Products and shall be available for BAXTER's use solely in connection with the Production of Products for CLIENT. BAXTER shall not use such equipment for any other purpose, shall not transfer such equipment to any third party or other location, shall not purport to convey or grant to any third party an interest in such equipment, and shall take no action inconsistent with CLIENT's ownership of such equipment. During the term of this Agreement, BAXTER shall be responsible for maintaining, servicing and insuring (including by means of self-insurance) such equipment to the same extent and in the same manner as BAXTER maintains,

services and insures (including by means of self- insurance) its own equipment. BAXTER shall maintain appropriate records regarding the use, maintenance and service of such equipment. Upon termination of this Agreement, BAXTER promptly shall deliver such equipment to CLIENT at such location as CLIENT reasonably requests.

#### Article 10, REGULATORY

10.1 **Regulatory Approvals**. In accordance with the Product Master Plan, CLIENT will diligently pursue Regulatory Approval of marketing licenses for Products Produced by BAXTER hereunder. CLIENT will advise BAXTER of document requirements in support of BLA and similar applications required of foreign governments and agencies including amendments, license applications, supplements and maintenance of such. BAXTER will provide documents and assist CLIENT in preparation of submissions to Regulatory Authorities (both U.S and foreign) designated by CLIENT in support of CLIENT's BLAs, similar applications required of foreign governments and licenses. All regulatory submission preparation and maintenance performed by BAXTER for CLIENT shall be specified in the Product Master Plan.

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#### 10.2 Regulatory Authority Inspections.

- 10.2.1 **Interaction with Regulatory Authorities.** All interaction with Regulatory Authorities (both written and oral) that directly affects Product or the Production of Product shall be conducted in accordance with the provisions of this Article 10. At CLIENT's request, BAXTER will authorize Regulatory Authorities to review on CLIENT's behalf applications related to the Production of Products.
- 10.2.2 **Product Pre-Approval Inspection.** In the case of the Product Pre-Approval Inspection by the FDA related to the Products, the following shall apply: (a) BAXTER immediately shall inform CLIENT of the notice of such inspection; (b) BAXTER shall permit a representative of CLIENT (who shall be selected by BAXTER from a list of senior representatives reasonably provided by CLIENT) to be present at such inspection (but not to participate, except as requested by BAXTER); (c) BAXTER shall permit such representative of CLIENT to be present at, and participate in, each daily wrap up session for such inspection and the post-inspection wrap up session for such inspection; (d) BAXTER promptly shall provide CLIENT with copies of all written materials, including without limitation copies of any Notice of Inspection (FDA Form 482), other notice of inspection, notice of violation, other similar notice, or Inspectional Observations (FDA Form 483) received by BAXTER relating to such inspection, and (e) BAXTER shall provide CLIENT with advance copies of all proposed responses to any such inspections, notices or actions, shall permit CLIENT reasonable opportunity to review and comment on each such response, shall reasonably consider CLIENT's reasonable comments thereon, and shall provide CLIENT with copies of each such response as submitted.
- 10.2.3 Other Product Specific Inspections. In the case of an inspection (other than the Product Pre-Approval Inspection) by a Regulatory Authority that directly affects the Production of Products, the following shall apply: (a) BAXTER immediately shall inform CLIENT of the notice of such inspection; (b) BAXTER shall permit a representative of CLIENT (who shall be selected by BAXTER from a list of senior representatives reasonably provided by CLIENT) to be present at the BAXTER facility that is the subject of such inspection (but not to be present at the inspection or to participate, except as requested by BAXTER); (c) BAXTER shall permit such representative of CLIENT to be present at, and participate in, each daily wrap up session for such inspection and the post-inspection wrap up session for such inspection; (d) BAXTER promptly shall provide CLIENT with copies of all written materials, including without limitation copies of any Notice of Inspection (FDA Form 482), other notice of inspection, notice of violation, other similar notice, or Inspectional Observations (FDA Form 483) received by BAXTER relating to such inspection, and (e) BAXTER shall provide CLIENT with advance copies of all proposed responses to any such inspections, notices or actions, shall permit CLIENT reasonable opportunity to review and comment on each such response, shall reasonably consider CLIENT's reasonable comments thereon, and shall provide CLIENT with copies of each such response as submitted.

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- 10.2.4 **Other Inspections.** In the case of an inspection by a Regulatory Authority of a Baxter facility that does not directly affect the Production of Products, the following shall apply: (a) BAXTER promptly shall provide CLIENT with copies of all written materials (with confidential information that does not directly affect the Production of Products redacted therefrom), including without limitation copies of any Notice of Inspection (FDA Form 482), other notice of inspection, notice of violation, other similar notice, or Inspectional Observations (FDA Form 483) received by BAXTER relating to such inspection; and (b) BAXTER promptly shall provide CLIENT with copies of all responses to any such inspections, notices or actions (with confidential information that does not directly affect the Production of Products redacted therefrom).
- Accelerated Delivery of Kits. In the event of any adverse regulatory action, including without limitation receipt by BAXTER from the FDA or other Regulatory Authorities of a warning letter, injunction, restraining order, notice of intent to do any of the foregoing, or notice of intent to revoke or suspend any of BAXTER's licenses that directly affect Product or the Production of Product, BAXTER shall deliver to CLIENT, within forty eight (48) hours of a written request from CLIENT and after tender by CLIENT of the applicable Purchase Price, all Kits and Kit Components requested by CLIENT in BAXTER's possession; provided that BAXTER is not prohibited from doing so per any applicable law, regulation, court or agency order, notice, or ruling.

#### **Article 11, TRADEMARKS**

- 11.1 CLIENT grants to BAXTER a non-exclusive, royalty free license to use the CLIENT Trademarks for the sole purpose of allowing BAXTER to fulfill its responsibilities under this Agreement. Such license shall not be transferable in whole or in part.
- 11.2 CLIENT shall be solely responsible for selecting, registering and enforcing the CLIENT Trademarks used to identify a Product and except as set forth in Section 11.1 and shall have sole and exclusive rights in such CLIENT Trademarks.

#### Article 12, REPRESENTATIONS AND WARRANTIES

Mutual Representations. Each party hereby represents and warrants to the other party that (a) the person executing this Agreement is authorized to execute this Agreement; (b) this Agreement is legal and valid and the obligations binding upon such party are enforceable by their terms; and (c) the execution, delivery and performance of this Agreement does not violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

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- BAXTER Warranties. BAXTER represents and warrants that, as of the time of delivery to CLIENT in accordance with this Agreement, all Product Produced under this Agreement (a) conforms to the Kit Component Specifications and/or Kit Specifications (as applicable), (b) has been Produced in accordance with cGMP and all applicable laws and regulations set forth in the Product Master Plan and in accordance with the applicable Certificates of Analysis (provided in accordance with the Quality Agreement) accompanying each Batch of Product, and (c) is not adulterated or misbranded within the meaning of the FD&C Act. BAXTER represents and warrants that it has obtained (or will obtain prior to Producing Product), and will remain in compliance with during the term of this Agreement, all permits, licenses and other authorizations (the "Permits") which are required under federal, state and local laws, rules and regulations applicable to the Production only of Product as specified in the Product Master Plan; provided, however, BAXTER shall have no obligation to obtain Permits relating to the sale, marketing, distribution or use of Products or with respect to the labeling of Products.

  BAXTER makes no representation or warranty with respect to the sale, marketing, distribution or use of Bulk Conjugated Antibody, other CLIENT Supplied Components or Products or as to printed materials specified by CLIENT or its consignee. BAXTER represents and warrants that (i) no BAXTER employees performing services on behalf of BAXTER under this Agreement have been debarred under Section 306 of the FD&C Act, and (ii) to its knowledge, no persons (other than BAXTER employees) performing services on behalf of BAXTER under this Agreement have been debarred under Section 306 of the FD&C Act.
- Disclaimer of Warranties. Except for those warranties set forth in Sections 12.1 and 12.2 of this Agreement, BAXTER makes no warranties, written, oral, express or implied, with respect to Product or the Production of Product. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY BAXTER. NO WARRANTIES OF BAXTER MAY BE CHANGED BY ANY REPRESENTATIVES OF BAXTER. CLIENT accepts Product subject to the terms hereof.
- 12.4 **CLIENT Warranties**. CLIENT warrants that it has the right to give BAXTER any information provided by CLIENT hereunder, and that BAXTER has the right to use such information for the Production of Product. CLIENT further warrants that the Bulk Conjugated Antibody and other CLIENT Supplied Components provided to BAXTER hereunder will (1) conform to the applicable Kit Component Specifications and/or Kit Specifications and (2) not be adulterated or misbranded within the meaning of the FD&C Act.
- Disclaimer of Warranties. Except for those warranties set forth in Section 12.4 of this Agreement, CLIENT makes no warranties, written, oral, express or implied, with respect to Bulk Conjugated Antibody, other CLIENT Supplied Components or Products. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY CLIENT. NO WARRANTIES OF CLIENT MAY BE CHANGED BY ANY REPRESENTATIVES OF CLIENT. BAXTER accepts Bulk Conjugated Antibody and other CLIENT Supplied Components subject to the terms hereof.

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# Article 13, LIMITATION OF LIABILITY, WAIVER OF SUBROGATION AND REPLACEMENT OF BULK CONJUGATED ANTIBODY AND OTHER CLIENT SUPPLIED COMPONENTS

- Limitation of Liability. Under no circumstances shall either party be liable to the other for loss of use or profits or other collateral, special, consequential, incidental or punitive damages, including but not limited to the cost of a recall, except as set forth in Sections 14 and 16, whether such claims are founded in tort or contract. Without limiting the generality of the foregoing and notwithstanding anything to the contrary herein, [CONFIDENTIAL TREATMENT REQUESTED].
- Waiver of Subrogation. All BAXTER Supplied Components and equipment used by BAXTER in the Production of Product, other than those Components and equipment that are specifically stated in this Agreement to be owned by CLIENT (collectively, "BAXTER Property"), shall at all times remain the property of BAXTER and BAXTER assumes risk of loss for the BAXTER Property until delivery of Product to a common carrier as specified under Section 6.1. BAXTER hereby waives any and all rights of recovery against CLIENT and its Affiliates, and against any of their respective directors, officers, employees, agents or representatives, for any loss or damage to BAXTER Property to the extent the loss of damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement).
- 13.3 **Replacement of Bulk Conjugated Antibody.** Risk of loss and responsibility for the cost of lost Bulk Conjugated Antibody shall be as follows:
  - 13.3.1 [CONFIDENTIAL TREATMENT REQUESTED].
  - 13.3.2 [CONFIDENTIAL TREATMENT REQUESTED].
  - 13.3.3 [CONFIDENTIAL TREATMENT REQUESTED].

- 13.3.4 Except as otherwise set forth in Sections 13.3.1, 13.3.2 and 13.3.3, with respect to Products determined to be non-conforming in any calendar year under Section 7.2, [CONFIDENTIAL TREATMENT REQUESTED].
- 13.3.5 Except as otherwise set forth in Sections 13.3.1, 13.3.2 and 13.3.3, [CONFIDENTIAL TREATMENT REQUESTED].
- 13.3.6 For purposes of this Section 13.3 the replacement cost for Bulk Conjugated Antibody shall be [CONFIDENTIAL TREATMENT REQUESTED].
- 13.3.7 [CONFIDENTIAL TREATMENT REQUESTED].
- 13.3.8 [CONFIDENTIAL TREATMENT REQUESTED].
- 13.4 **Replacement of Other CLIENT Supplied Components.** Risk of loss and responsibility for the cost of lost [CONFIDENTIAL TREATMENT REQUESTED], shall be borne solely by [CONFIDENTIAL TREATMENT REQUESTED].
- 13.5 [CONFIDENTIAL TREATMENT REQUESTED].

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#### **Article 14, INDEMNIFICATION**

- 14.1 CLIENT Indemnification. CLIENT shall indemnify, defend and hold harmless BAXTER and its Affiliates and any of their respective directors, managers, members, officers, employees, authorized subcontractors and agents (collectively the "Indemnified Parties") from and against any and all liabilities, obligations, penalties, judgments, disbursements of any kind and nature, losses, damages, costs and expenses (including, without limitation, reasonable attorney's fees and costs) incurred as a result of any claims, demands, actions or other proceedings by unaffiliated third parties against an Indemnified Party [CONFIDENTIAL TREATMENT REQUESTED] arising out of property damage or personal injury (including without limitation death) of third parties (collectively "Claims"), resulting from [CONFIDENTIAL TREATMENT REQUESTED].
- 14.2 **BAXTER Indemnification**. BAXTER shall indemnify, defend and hold harmless CLIENT and its Affiliates and any of their respective directors, officers, employees, and agents from and against any and all Claims resulting [CONFIDENTIAL TREATMENT REQUESTED].
- Indemnitee Obligations. A party (the "Indemnitee") which intends to claim indemnification under this Section 14 shall promptly notify the other party (the "Indemnitor") in writing of any claim, demand, action, or other proceeding in respect of which the Indemnitee intends to claim such indemnification; provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee shall permit, and shall cause its Affiliates, and their respective directors, officers, employees, subcontractors and agents to permit, the Indemnitor, at its discretion, to settle any such action, claim or other matter, and the Indemnitee agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitee in addition to those set forth herein, in order for it to exercise such rights, without Indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitor, which shall not be unreasonably withheld or delayed. The Indemnitee, its Affiliates, and their respective directors, officers, employees, subcontractors and agents shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation and defense of any claim, demand, action, or other proceeding covered by the indemnification obligations of this Section 14. The Indemnitee shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

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#### **Article 15, INSURANCE**

- 15.1 CLIENT Insurance. CLIENT shall procure and maintain, during the Term of this Agreement and for a period one (1) year beyond the expiration date of the last Product Produced under this Agreement, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the "CLIENT Insurance"). The CLIENT Insurance shall cover amounts not less than [CONFIDENTIAL TREATMENT REQUESTED] combined single limit and shall be with an insurance carrier reasonably acceptable to BAXTER. BAXTER shall be named as an additional insured on the CLIENT Insurance and CLIENT promptly shall deliver a certificate of CLIENT Insurance and endorsement of additional insured to BAXTER evidencing such coverage. If CLIENT fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement BAXTER is notified of the cancellation or lapse of the CLIENT Insurance, and CLIENT fails to rectify the same within ten (10) calendar days after notice from BAXTER, in addition to all other remedies available to BAXTER hereunder, BAXTER, at its option, may obtain the CLIENT Insurance and CLIENT promptly shall reimburse BAXTER for the cost of the same. Any deductible and/or self insurance retention shall be the sole responsibility of CLIENT.
- BAXTER Insurance. BAXTER is, and shall during the Term of this Agreement remain, self-insured for the type of liability that could arise under this Agreement, to the same extent and in the same manner as BAXTER maintains self-insurance for similar activities. Notwithstanding the foregoing, except in the case of an assignment of this Agreement by BAXTER to an Affiliate of Baxter Healthcare Corporation, unless CLIENT otherwise reasonably agrees, any permitted assignee or successor in interest to BAXTER under this Agreement (the "Successor") shall procure and maintain, during the Term of this Agreement and for a period one (1) year beyond the expiration date of the last Product Produced under this Agreement, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the "Successor Insurance"). The Successor Insurance shall cover amounts not less than [CONFIDENTIAL TREATMENT REQUESTED] combined single limit and shall be with an insurance carrier reasonably acceptable to CLIENT. CLIENT shall be named as an additional insured on the Successor Insurance and Successor

promptly shall deliver a certificate of Successor Insurance and endorsement of additional insured to CLIENT evidencing such coverage. If Successor fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement CLIENT is notified of the cancellation or lapse of the Successor Insurance, and Successor fails to rectify the same within [CONFIDENTIAL TREATMENT REQUESTED] after notice from CLIENT, in addition to all other remedies available to CLIENT hereunder, CLIENT, at its option, may obtain the Successor Insurance and Successor promptly shall reimburse CLIENT for the cost of the same. Any deductible and/or self insurance retention shall be the sole responsibility of Successor.

#### Article 16, RECALL OF PRODUCT

Each party promptly shall notify the other if any Batch of Product is alleged or proven to be the subject of a recall, market withdrawal or correction. CLIENT shall be responsible for coordinating any recall, market withdrawal or field correction of Product, and recall, market withdrawal or correction shall be conducted in accordance with the provisions of the Quality Agreement. CLIENT shall provide BAXTER with a copy of all documents relating to such recall, market withdrawal or field correction. BAXTER shall cooperate with CLIENT (including providing CLIENT with all data, information and documents requested by CLIENT) in connection with such recall, market withdrawal or field correction, at CLIENT's expense. [CONFIDENTIAL TREATMENT REQUESTED]

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[CONFIDENTIAL TREATMENT REQUESTED] Recall Class						
Number of Consignees	I	п	III			
			N/A			
			N/A			
			N/A			

In the event a recall, market withdrawal or field correction is necessary because [CONFIDENTIAL TREATMENT REQUESTED].

16.2 [CONFIDENTIAL TREATMENT REQUESTED].

#### **Article 17, INTELLECTUAL PROPERTY**

- Existing Intellectual Property. Except as the parties may otherwise expressly agree in writing, each party shall continue to own its existing patents, trademarks, copyrights, trade secrets and other intellectual property, without conferring any interests therein on the other party. Without limiting the generality of the preceding sentence, CLIENT shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable United States and foreign laws, rules and regulations relating to Product, Bulk Conjugated Antibody, CLIENT Supplied Components, labeling and trademarks associated therewith (collectively, "CLIENT's Intellectual Property"). Neither BAXTER nor any third party shall acquire any right, title or interest in CLIENT's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.
- Individually Owned Inventions. Except as the parties may otherwise agree in writing, all Inventions (as defined herein) which are conceived, reduced to practice, or created by a party in the course of performing its obligations under this Agreement shall be solely owned and subject to use and exploitation by the inventing party without a duty to account to the other party. For purposes of this Agreement, "Invention" shall mean any invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable. BAXTER hereby grants to CLIENT a royalty-free, non-exclusive, worldwide license (with the right to grant sublicenses) under all patent rights and other intellectual property rights covering Inventions which are conceived, reduced to practice, or created by BAXTER in the course of performing its obligations under this Agreement and which relate directly to the Bulk Conjugated Antibody or other CLIENT Supplied Components.

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Jointly Owned Inventions. All Inventions which are conceived, reduced to practice, or created jointly by the parties and/or their respective agents (i.e., employees or agents who would be or are properly named as co-inventors under the laws of the United States on any patent application claiming any such Invention) in the course of the performance of this Agreement shall be owned jointly by the parties. Each party shall have full rights, subject to the provisions of this Agreement, to freely exploit, transfer, license or encumber its rights in any such jointly-owned Inventions and the patent rights and other intellectual property rights therein without the consent of, or payment or accounting to, the other party. The parties shall share equally in the cost of mutually agreed patent filings with respect to all such jointly owned Inventions. The decision to file for patent coverage on jointly owned Inventions shall be mutually agreed upon, and the Parties shall select a mutually acceptable patent counsel to file and prosecute patent applications based on such joint Inventions.

**Disclaimer.** Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as: (i) a grant, transfer or other conveyance by either party to the other of any right, title, license or other interest of any kind in any of its Inventions or intellectual property, (ii) creating an obligation on the part of either party to make any such grant, transfer or other conveyance or (iii) requiring either party to participate with the other party in any cooperative development program or project of any kind or to continue with any such program or project.

- 17.5 **Rights in IP**. The party owning any solely-owned Invention shall have the world wide right to control the drafting, filing, prosecution and maintenance of patents covering such solely-owned Invention, including decisions about the countries in which to file patent applications. Patent costs associated with the patent activities described in this Section shall be borne by the sole owner. Each party will cooperate with the other party, at the sole cost of the other party, in the filing and prosecution of patent applications covering Inventions solely owned by the other party. Such cooperation will include, but not be limited to, furnishing supporting data and affidavits for the prosecution of patent applications and completing and signing forms needed for the prosecution, assignment and maintenance of patent applications.
- Confidentiality of IP. The protection of each party's Confidential Information is described in Section 18. Any disclosure of information by one party to the other under the provisions of this Section 17 shall be treated as the disclosing party's Confidential Information under this Agreement (subject to the exceptions set forth in Section 1 of the Confidentiality Agreement). It shall be the responsibility of the party preparing a patent application to obtain the written permission of the other party to use or disclose the other party's Confidential Information in the patent application before the application is filed and for other disclosures made during the prosecution of the patent application.

#### Article 18, CONFIDENTIAL INFORMATION, NONDISCLOSURE AND PUBLICITY

Confidentiality. It is contemplated that in the course of the performance of this Agreement each party may, from time to time, disclose Confidential Information to the other. In accordance with the terms and conditions of the Confidentiality Agreement, each party shall maintain in confidence the Confidential Information of the other party, shall not use or grant the use of the Confidential Information of the other party except as expressly permitted hereby, and shall not disclose the Confidential Information of the other party except on a need-to-know basis to such party's directors, officers and employees to the extent such disclosure is reasonably necessary in connection with such party's activities as expressly authorized by this Agreement.

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- Prior Confidentiality Agreement. The Confidentiality Agreement, by reference, is made a part hereof as though fully set forth herein. The Parties acknowledge that BAXTER is the successor by assignment to Baxter Healthcare Corporation under the Confidentiality Agreement, and BAXTER shall be bound by the terms of the Confidentiality Agreement to the same extent as if BAXTER were an original signatory thereto. The Confidentiality Agreement is amended (a) to govern all disclosures by the parties hereunder, and [CONFIDENTIAL TREATMENT REQUESTED].
- Third Party Disclosure. Either party may disclose Confidential Information of the disclosing party to those Affiliates, agents and consultants who need to know such information to accomplish the purposes of this Agreement (collectively, "Permitted Recipients"); provided that such Permitted Recipients are bound to maintain such Confidential Information in confidence to the same extent as set forth in Section 18.1.
- 18.4 **Litigation and Governmental Disclosure**. Each party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable laws, governmental regulations or court orders, or conducting pre-clinical or clinical trials, provided that if a party is required by law or regulation to make any such disclosure of the other party's Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other party of such disclosure requirement and will use good faith efforts to assist such other party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.
- 18.5 **Limitation of Disclosure**. The parties agree that, except as otherwise may be required by applicable laws, regulations, rules or orders, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission, and except as may be authorized in Section 18.4, no information concerning this Agreement and the transactions contemplated herein shall be made public by either party without the prior written consent of the other.
- Publicity and SEC Filings. The parties agree that the public announcement of the execution of this Agreement shall only be by one or more press releases mutually agreed to by the parties. The failure of a party to return a draft of a press release with its proposed amendments or modifications to such press release to the other party within [CONFIDENTIAL TREATMENT REQUESTED] of such party's receipt of such press release shall be deemed as such party's approval of such press release as received by such party. Each party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of Confidential Information of either party included in any such disclosure.

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### Article 19, FORCE MAJEURE

Any delay in the performance of any of the duties or obligations of either party hereto (except the payment of money), to the extent caused by an event outside the affected party's reasonable control, shall not be considered a breach of this Agreement, and unless provided to the contrary herein, the time required for performance shall be extended for a period equal to the period of such delay. Such events shall include without limitation, acts of God; acts of public enemies; insurrections; riots; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; floods; shortages of material or energy; delays in the delivery of raw materials; acts or orders of any government or agency thereof or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the party so affected. The party so affected shall give prompt written notice to the other party of such cause and a good faith estimate of the continuing effect of the force majeure condition and duration of the

affected party's nonperformance, and shall take whatever reasonable steps are appropriate to relieve the effect of such causes as rapidly as possible. [CONFIDENTIAL TREATMENT REQUESTED].

#### Article 20, NOTICES

20.1 All notices hereunder shall be delivered by facsimile (confirmed by overnight delivery), or by overnight delivery with a reputable overnight delivery service, to the following address of the respective parties:

If to BAXTER: Baxter Pharmaceutical Solutions LLC

927 South Curry Pike Bloomington, Indiana 47403

Attn: Alisa K. Wright, Vice President of Business Affairs

Telefax No. 812-332-3079 Telephone No. 812-333-0887

With a copy to: Baxter Healthcare Corporation

One Baxter Parkway

Deerfield, Illinois 60015-4633 Attn: General Counsel

Telefax No. (847) 948-2450 Telephone No. (847) 948-2600

If to CLIENT: IDEC Pharmaceuticals Corporation

3030 Callan Road

San Diego, California 92121

Attn: President

Telefax No. (858) 431-8755 Telephone No. (858) 431-8500

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With a copy to: IDEC Pharmaceuticals Corporation

3030 Callan Road

San Diego, California 92121 Attn: Company Secretary

Telefax No. (858) 431-8755 Telephone No. (858) 431-8500

Notices shall be effective on the day of receipt. A party may change its address listed above by notice to the other party given in accordance with this section.

#### Article 21, APPLICABLE LAW

This Agreement is being delivered and executed in the State of Indiana. In any action brought regarding the validity, construction and enforcement of this Agreement, it shall be governed in all respects by the laws of the State of Indiana, without regard to the principals of conflicts of laws.

#### Article 22, ASSIGNMENT

22.1 Neither party shall assign this Agreement or any part hereof or any interest herein to any third party (or use any subcontractor) without the written approval of the other party. In addition, no consent shall be required (a) in the case of an assignment by BAXTER to an Affiliate of Baxter Healthcare Corporation, or (b) in the case of a transaction involving the merger, consolidation, change in control or sale of all or substantially all of the assets of the party seeking such assignment or transfer and such transaction relates to the business covered by this Agreement and the resulting entity assumes all of the obligations under this Agreement. No assignment shall be valid unless the permitted assignee(s) assumes all obligations of its assignment in violation of this section shall be void.

# Article 23, ALLIANCES

Notwithstanding anything to the contrary herein, BAXTER agrees that CLIENT shall have the right to enter into alliances with third parties who may engage in joint (with CLIENT) or unilateral marketing and promoting of Product or any combination of products that includes Product.

#### Article 24, TAXES

CLIENT shall pay all national, state, municipal or other sales, use, excise, import, property, value added, or other similar taxes, assessments or tariffs assessed upon or levied against the sale of Product to CLIENT pursuant to this Agreement or the sale or distribution of Product by CLIENT (or at CLIENT's sole expense, defend against the imposition of such taxes and expenses). BAXTER shall notify CLIENT of any such taxes that any governmental authority is seeking to collect from BAXTER, and CLIENT may assume the defense thereof in BAXTER's name, if necessary, and BAXTER agrees to fully cooperate in such defense to the extent of the capacity of BAXTER, at CLIENT's expense. BAXTER shall pay all national, state, municipal or other taxes on the income resulting from the sale by BAXTER of Product to CLIENT under this Agreement, including but not limited to, gross income, adjusted gross income, supplemental net income, gross receipts, excess profit taxes, or other similar taxes.

#### Article 25, SUCCESSORS AND ASSIGNS

25.1 This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their successors and permitted assigns.

#### **Article 26, ENTIRE AGREEMENT**

26.1 This Agreement, together with the Product Master Plan and the Confidentiality Agreement, constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes all written or oral prior agreements, understandings and representations with respect thereto.

#### Article 27, SEVERABILITY

27.1 If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

#### Article 28, WAIVER AND MODIFICATION OF AGREEMENT

No waiver or modification of any of the terms of this Agreement (including the [CONFIDENTIAL TREATMENT REQUESTED] hereto), the Product Master Plan or the Confidentiality Agreement, shall be valid unless in writing and signed by an authorized representative of each party. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

#### **Article 29, INDEPENDENT CONTRACTORS**

29.1 BAXTER and CLIENT are acting under this Agreement as independent contractors and neither shall be considered an agent of, or joint venturer with, the other.

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**IN WITNESS WHEREOF,** the parties have caused this Commercial Supply Agreement to be signed by their duly authorized representatives as of the Effective Date written above.

Effective I	Date written above.		
	"BAXTER"		"CLIENT"
BAXTER	PHARMACEUTICAL SOLUTIONS LLC	IDEC PHAR	MACEUTICALS CORPORATION
Ву:		By:	
Name:	Alisa Wright	Name:	
Title:	Vice President	Title:	
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# IDEC PHARMACEUTICALS CORPORATION AND SUBSIDIARY COMPUTATION OF RATIO OF EARNINGS TO FIXED CHARGES (1) (in thousands, except ratios)

Years Ended December 31,

	2002	2001	2000
Income before income tax provision	231,522	161,604	69,347
Fixed charges:			
Interest expense and amortization of original issue discount on all indebtedness	16,073	7,304	7,053
Interest included in rent expense	1,541	1,120	889
Total fixed charges	17,614	8,424	7,942
Income before income tax provision and fixed charges	249,136	170,028	77,289
Ratio of earnings to fixed charges	14.14	20.18	9.73

<sup>(1)</sup> The ratio of earnings to fixed charges was computed by dividing earnings (income before income tax provision, adjusted for fixed charges) by fixed charges for the periods indicated. Fixed charges include (i) interest expense and amortization of original issue discount on all indebtedness and (ii) a reasonable approximation of the interest factor deemed to be included in rental expense.

#### INDEPENDENT AUDITORS' CONSENT

The Board of Directors IDEC Pharmaceuticals Corporation:

We consent to incorporation by reference in the registration statements (Nos. 333-97211, 333-65494, 333-47904 and 333-81625) on Form S-8 and in the registration statement (No. 333-89792) on Form S-3 of IDEC Pharmaceuticals Corporation of our report dated January 29, 2003, relating to the consolidated balance sheets of IDEC Pharmaceuticals Corporation and subsidiaries as of December 31, 2002 and 2001, and the related consolidated statements of income, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2002, and the related consolidated financial statement schedule, which report appears in the 2002 Annual Report on Form 10-K of IDEC Pharmaceuticals Corporation.

/s/ KPMG LLP

San Diego, California March 27, 2003